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Validation and Clinical Evaluation of a Digital Wound Management Checklist

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The research objective was to explore how a medical device software called the Wound Navigator affects the clinical decision-making process, and to analyse the usability of the Wound Navigator in clinical settings. Another objective was to gain knowhow and produce suggestions on how to execute validation activities and gain insights to complement clinical evaluation of a medical device at Helsinki University Hospital IT Management.

The research was conducted as case study research. The data collection was executed in two parts. First part represented the validation activities in the medical device product development process, and it was conducted as an end-user testing. The end-users tested the Wound Navigator with fictional patient cases. In addition to testing, testers were interviewed regarding the usability of the Wound Navigator and overall experiences regarding digital checklists. The entire end-user testing was observed when possible, and any findings relating to the use of Wound Navigator were noted. The second part of data collection complemented the clinical evaluation in the medical device product development process. Expert statements were collected from wound management professionals to evaluate the clinical accuracy and usefulness of the Wound Navigator.

The structural approach in the Wound Navigator was viewed to support the clinical decision-making process. Majority of testers reported that the procedure recommendations were clear and concise. Overall, the feedback of the usability of the Wound Navigator was positive, and some development recommendations were collected. The expert statements agreed that the flowcharts of the Wound Navigator were clinically accurate.

Based on the findings, it was concluded that there is an unmet need for digital checklists, especially as literature has shown that use of checklists can decrease adverse effects in health care. The importance of end-user involvement in the development was highlighted in order to develop timesaving, usable and truly beneficial tools. The findings of this research could be implemented to practice when developing new medical device software.

Key words
Medical device, software, usability, wound care, digitalisation

CONTENTS

1 INTRODUCTION

Technological advancements and health care digitalisation are the norm in today's work environments. Health care professionals face various digital tools on daily basis, and the number of software and applications is ever-increasing. (van Velsen, Beaujean & van Gemert-Pijnen 2013, 1-2.) Still, the decision-making process relies greatly on the professionals' expertise; what they have learned during their education, what experiences have they gained over their career. In a way, professionals have sophisticated checklists and decision trees in their head, which have developed over time. (Antes, Dineen, Bakanas, Zahrli, Keune, Schuelke & DuBois 2020, 2.) There are, however, situations where physicians might benefit from tools that support their own decision-making process; patient cases which they have not yet developed an intrinsic decision tree for.

This case study focuses on one of such tools, called the Wound Navigator. The Wound Navigator is a medical device software, which supports the decision-making process regarding management of chronic wounds. Chronic wounds can be difficult to assess due to the possible complexity of the aetiology of the wound. Especially for physicians who do not treat wound patients often can find the assessment difficult. The Wound Navigator provides wound patient assessment checklist available for professionals who need support for the decision-making. It has been developed by wound management experts, who treat complex wounds daily.

When a checklist or decision tree is produced as a software, its most likely a medical device. A medical device or medical device software must be developed according to quality standards, in order to ensure its safety, reliability and high quality. One part of the medical device development is the validation activities and clinical evaluation. (Regulation (EU) on medical devices 2017/745, articles 2, 5). This case study focuses on the validation activities and clinical evaluation of the Wound Navigator. The validation refers to clinical performance, which means the ability of the device to produce clinically accurate results compared with the intended purpose. Clinical performance

can be demonstrated by usability assessment, which is the approach in this thesis (Medical Device Coordination Group 2020, 14).

This thesis consists of two parts: the first part presents the background and theoretical framework, and the second part consists of report of the practical execution. The background and theoretical framework explain the criticality of wound management, describes the current status of health care digitalisation, and reflects the use of checklists in health care. In addition, the background and theoretical framework discusses the usability of digital tools and presents the medical device regulation. Special features of the case study's context are also described. The practical execution presents how the validation activities and collection of insights for clinical evaluation were carried out. It is described how the Wound Navigator affects the clinical decision-making process based on the end-user testing and explains the findings collected regarding the usability of the Wound Navigator in clinical setting. Lastly, the thesis discusses the use of digital checklists in clinical setting together with ideas how validation and clinical evaluation could be executed for similar devices as the Wound Navigator. The thesis concludes the reporting through reflecting the research process and proposing future research topics.

2 BACKGROUND

A change in population structure, both nationally and globally, is evident in all fields of economy. Finnish population is aging, due to decreasing birth rates while advancements in health care is leading to people living longer (Aalto, Ahola, Hytönen, Paavonen, Palmén, Pääkkönen & Tamminen 2020, 10, 14). Longer lives are followed by increase in chronic conditions leading to higher health care expenditures (Allen 2019, 9). This imposes pressure to national economy (Aalto, Ahola, Hytönen, Paavonen, Palmén, Pääkkönen & Tamminen 2020, 10). In Finland, health care expenditure rose 1,2% from 2017 to 2018, amounting totally over 21 billion euros (Matveinen 2020, 1). Globally, it is estimated that health expenditure will rise 5% annually

during 2019-2023 (Allen 2019, 2). One patient group which imposes significant health care costs is chronic wound patients. Longer lives and increases in the prevalence of chronic conditions, such as diabetes, autoimmune diseases, neuropathies, and cardiovascular conditions has increased the number of chronic wound patients over the recent years. (Las Heras, Igartua, Santos-Vizcaino & Hernandez 2020, 532.)

One aspect how to tackle the ever-increasing costs of health care is utilisation of technology. Health care digitalisation has been seen to promote cost-effectiveness and efficiency in health care, while improving equal service offering and promoting health and welfare. (Hyppönen & Ilmarinen 2016, 1.) Driving factors to health care digitalisation include not only technology advancements, but also the willingness to use digital services by the general public, changes in the operating culture, and national guidance and incentives. Digitalisation encompasses change; changes in work operations and processes, roles, organisations, and business functions. In order to achieve the full potential of health care digitalisation, users should be placed in the centre of the development. (Saranto, Kinnunen, Jylhä & Kivekäs 2020, 179, 184.)

In the following chapter costs of wound management for the society and individual are presented in more detail. In addition, strategies how wound management should be carried out are explained. The concept of health care digitalisation and its relation to health care cost handling is presented in chapter 2.2. Chapter 2.2.1 presents a practical example of health care digitalisation effort produced during a government-funded project. Lastly, in chapter 2.2.2 the Wound Navigator is explained.

2.1 Wound Management

Wounds have a profound effect both on an individual and societal level, amounting for substantial health care expenditure while having a drastic effect on quality of life (Lindholm & Searle 2016, 5). Wound care accounts for a significant amount of health care costs, ranging from 2% up to over 5% of total annual health care expenditure (Lindholm & Searle 2016, 6; Gottrup, Henneberg, Trangæk, Bækmark, Zøllner & Sørensen 2013, 413; Phillips, Humphreys, Fletcher, Harding, Chamberlain & Macey

2016, 1193). In Finland, it has been estimated that annual costs of chronic wound management account 190-270 million euros (Seppänen & Hjerppe 2007, 6). With increase in life expectancy together with growing numbers of chronic diseases such as diabetes, the prevalence of wounds is expected to increase further. For example, majority of hospital visits of diabetes patients are caused by chronic wounds. (Kaartinen, Berg & Lagus 2017, 481.)

On an individual level, chronic wounds have reported to decrease quality of life and to increase anxiety and depression. In addition, poor wound management strategy has been shown to decrease patient's engagement in wound care. (Wounds International 2012, 1.) Chronic wounds often relate to pain, reduced mobility, social isolation, distress and even chronic morbidity and mortality (Lindholm & Searle 2016, 5; Olsson, Järbrink, Divakar, Bajpai, Upton, Schmidtchen & Car 2019, 119). Thus, accurate wound management is vital both from individual and societal point of view.

A wound is considered to be chronic if it has not healed in four weeks. In ischemic and diabetic leg ulcers, chronicity is established after two weeks. The reason why a wound becomes chronic should always be diagnosed; often there is a chronic condition affecting the chronicity of a wound. (Ahmajärvi & Isoherranen 2017, 524.) The imperative aspect on wound management is well-executed clinical examination and history-taking, which form the foundation for the diagnosis and care (Krooninen alaraajahaava: Käypä hoito -suositus, 2014). The aetiology of the wound guides the clinical decision-making, selection of interventions and overall care plan. Without establishing the root cause on time, delayed diagnosis can lead to serious adverse effects and increased costs. (Ahmajärvi & Isoherranen 2017, 524-535.)

As wound patients often have several comorbidities, there is a need for additional support regarding wound management especially for general practitioners and clinicians who have limited experience of treating wound patients. Such support is provided by clinical guidelines and best practices, which are available for wound management. However, often these guidelines do not include a structured process for their implementation in practice. One solution to help adopt clinical guidelines to practice is the

use of checklists. (Snyder, Jensen, Applewhite, Couch, Joseph, Lantis & Serena 2019, S29-S30.)

2.2 Digitalisation in Health Care

In literature, few distinctive terms are used when different levels of digital approaches are described in health care context: digitisation, digitalisation, and digital transformation. Digitisation refers to transforming data into digital format. Digitalisation can be seen as utilisation of digital data with the help of digital technologies. Digital transformation refers to more profound change in the business models towards patient-centred services, that integrate technology, processes, and digital data. User-centred design and holistic understanding how business operations can transform is the heart of digital transformation. Digital transformation and digitalisation are used in parallel to each other in the literature referring to the holistic approach. (Saranto, Kinnunen, Jylhä & Kivekäs 2020, 184; Moisil 2019, 1.) For clarification, in this report digitalisation will be used as the term referring to the holistic approach.

As mentioned earlier, the driving forces for health care digitalisation include increasing health care expenditure, rapid technology advancements together with requirements and expectations of the general public, national policies, and changes in the business environment. In addition to national policies, European-wide guidance, such as digital by default principle, underline the importance of digitalisation activities in health care sector. Digital services should provide benefits for the users, be easy and safe to use, promote quality and diminish unnecessary contacts to health care. Digitalisation should not solely aim at economic benefits or organisational status improvements, but rather focus on providing ethically sustainable solutions. (Garmann-Johnsen, Helmersen & Eikebrokk 2020, 247; Saranto, Kinnunen, Jylhä & Kivekäs 2020, 179, 185, 191).

Health care digitalisation has great expectations for resolving many of the issues health care sector is currently facing. Regardless of the potential it possesses, in literature there is evidence of several challenges it must overcome to fulfil those expectations.

Challenges to utilising health care digitalisation include being more cost than user-centred, increasing expenses rather than lowering them, and taking up professionals' time from patients (Moisil 2019, 1). In addition, user abilities and features, such as experience, skills and expectations regarding technology affect the utilisation of digital solutions (Gjellebæk, Svensson, Bjørkquist, Fladeby & Grundén 2020, 1).

Health care digitalisation focuses on placing the patient in the centre of care and there is an abundance of services, applications and devices for patients and general public. However, while patients expect professionals to guide them in the midst of application jungle, the professionals are getting more confused by the amount of data provided through various digital sources. (Meskó, Drobni, Bényei, Gergely & Győrffy 2017, 1.) Vast majority of digital solutions for professionals focuses mainly on electronic medical record systems (EMR). In the literature there are only few examples of digital solutions directed to professionals as end users other than EMRs.

The ability of professionals to utilise digital tools as part of their everyday clinical work is crucial for realisation of health care digitalisation benefits. Professionals' knowledge and understanding of the clinical processes is of great value which should be utilised already during the development of digital services. Co-creation can greatly improve the usability of digital tools in clinical setting as it promotes the involvement of professionals during each phase of product or service development. (Garmann-Johnsen, Helmersen & Eikebrokk 2020, 247; Häyrinen 2018, 186.)

Involving professionals in the development brings advantages additionally in terms of usability. It is noted that every second person has only limited skills in health literacy. This relates to likeliness of using digital health care applications, with lower health literacy skills relating to lower likeliness of digital application usage. (Meskó, Drobni, Bényei, Gergely & Győrffy 2017, 5.) Professionals evaluate systems from different perspective than usability designers or evaluators (Häyrinen 2018, 186). By involving professionals in the development of digital tools, this matter can be taken into account with advanced usability and user interface planning. With successful user interface planning, even complex digital systems can be easy to use without advanced digital skills (Meskó, Drobni, Bényei, Gergely & Győrffy 2017, 5).

With a help of digitalisation, utilisation of evidence-based care and best practices can further be promoted in clinical setting. It is noted, that implementing best practices can be difficult, while evidence-based care is the guarantee of quality care (Melnyk, Gallagher-Ford, Long & Fineout-Overholt 2014, 5-6). By developing digital tools which promote the implementation best practices improves the quality of care while supporting professionals in their everyday work (Saranto, Kinnunen, Jylhä & Kivekäs 2020, 192.). Especially for patients with complex disorders, diseases or multiple chronic conditions, such tools could provide additional aids for professionals to provide quality care.

2.2.1 Health Village and Health Village PRO

One practical example of health care digitalisation is Health Village. Health Village is a web-based service which provides health care services available for all regardless of their residence area. It brings together information regarding health, wellbeing, diseases and conditions, provides guidance on self-care, rehabilitation, and digital care pathways, promotes communication between professionals and patients and promotes professional learning, knowledge, and knowhow. Health Village was developed by the five Finnish university hospital districts during Virtual Hospital 2.0 -project in 2016-2018, and the development was partly financed by the Ministry of Social Affairs and Health. (Health Village, 2020.)

Health Village is built around three units: it contains services for the general public (Terveyskylä.fi), services for patients (Omapolku – My Path), and services for health care professionals (TerveyskyläPRO – Health Village PRO). All services are web-based and are accessible with a browser. In addition, Health Village has specific technological architecture and platform, and its unique development model for service production. (Health Village, 2020; Arvonen & Lehto-Trapnowski 2019, 3.)

Health Village PRO (TerveyskyläPRO) is the portal for health care professionals. It can be accessed by professionals who have registered as a user to the portal. Professionals can find best practice guidelines, symptom navigators, instructions how to work in digital environment and access remote consultation. Best practice guidelines cover variety of diseases and conditions. Remote consultations are available for specific speciality, such as neurology, and for selected health centres. There is also a search for rare diseases, which includes contact information for professionals who are specialised in those rare diseases.

Symptom navigators for professionals can support the professionals' decision-making process, such as during patient examination, clinical diagnostics, care, and medication. They follow predetermined decision trees, which can have several levels and branches. Navigators can be used to support the implementation of best practices in clinical work by providing a simple and quick tool to be used even during a patient appointment. The navigators in Health Village PRO are developed by specialists in their field and implement the current evidence-based practices. Some of the navigators are CE-marked medical devices, which have been developed according to regulations and specific quality system.

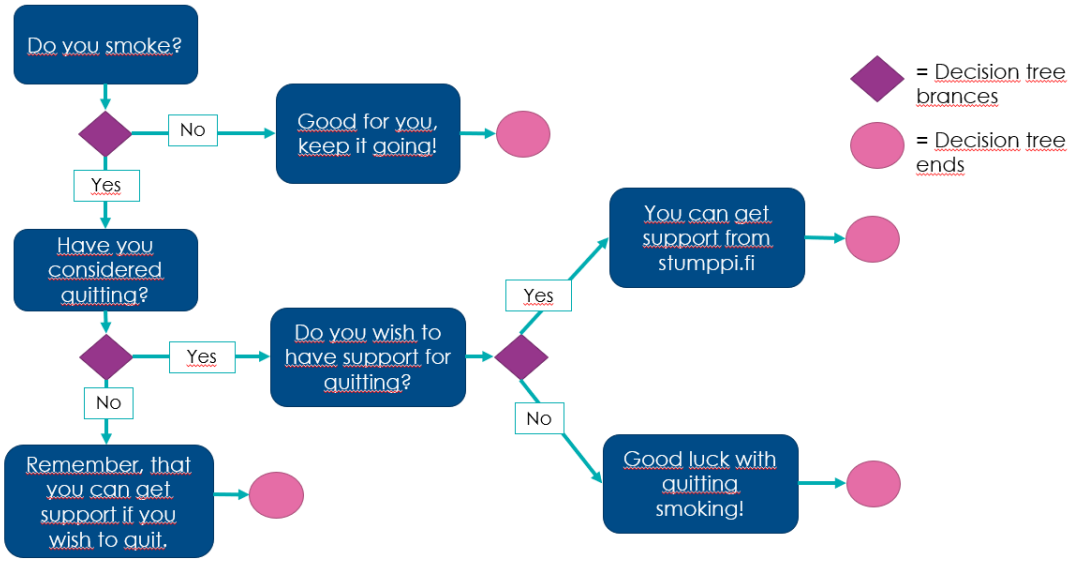

Figure 1. Example of a decision tree for symptom navigator

2.2.2 Wound Navigator in Health Village PRO

As mentioned before, the imperative aspect on wound management is well-executed clinical examination and history-taking (Krooninen alaraajahaava: Käypä hoito -suositus, 2014). The aetiology of the wound guides the clinical decision-making, and delayed diagnosis can lead to serious adverse effects and increased costs. (Ahmajärvi & Isoherranen 2017, 524-535.) Wound Navigator is a symptom navigator for physicians in Health Village PRO. As a checklist it supports systematic examination of a wound patient in order to promote a holistic approach to examination. The aim is to support the physician in finding the underlying cause for the wound as soon as possible.

Wound Navigator is developed in Helsinki University Hospital as a joint project with Wound Centre and IT Management. The content and logic are based on Current Care Guidelines. A physician should use Wound Navigator when a wound has not healed during two weeks; thus, it is not meant to use when caring for acute or traumatic wounds. Wound Navigator does not replace the clinical examination and when using the service, physician must be able to rule out other diseases according to one's clinical skills and knowledge.

Wound Navigator constitutes of seven different decision trees, based on the location of the wound. The location determines which decision tree the user is guided to. The user can select multiple wound locations simultaneously. Depending on the location, there are set of questions the user answers. The questions relate to the wound while noting any underlying conditions which can affect wound healing. Wound Navigator guides the user through the decision tree, and proceeds depending on the answers to previous questions. After the physician has answered all questions, Wound Navigator provides procedure recommendations for the physician.

The technology utilised allows complex decision trees, and it is provided as SaaS (Software as a Service). The contents of the decision trees are configurated in the product portal, however some developer skills are required during the configuration. The navigator is integrated into Health Village PRO web pages. It complements the virtual

centre for wounds, which provides large variety of best practice instructions and protocols for health care professionals.

3 PURPOSE, RESEARCH QUESTIONS AND OBJECTIVES

As health care is transforming towards digitalization, medical device technology market is estimated to grow substantially in the near future. In order to provide up-to-date digital services to patients and professionals, HUS IT Management is certified as a medical device manufacturer.

An integral part of medical device certification process is validation and clinical evaluation. The purpose of this research is to plan and undergo the validation activities and collect insights to complement the clinical evaluation for the Wound Navigator. In addition, based on the experiences collected during the project, suggestions for planning and executing medical device validation activities and clinical evaluation will be produced for HUS IT Management.

The research questions are the following:
1. How digital checklists can support the clinical decision-making in wound management?
2. How clinical professionals perceive the usability of digital checklists in clinical setting for wound management?
3. How validation activities and clinical evaluation can be executed as part of medical device product development process?

The research objective is to explore how Wound Navigator affects the clinical decision-making process, and to analyse the usability and usefulness of Wound Navigator in clinical settings. Another objective is to gain knowhow and produce suggestions for validation activities and clinical evaluation of a medical device at HUS IT Management.

4 THEORETICAL FRAMEWORK

This chapter represents the theoretical background regarding the research subject. Firstly, it presents how checklists are used in health care settings. The Wound Navigator represents a digital checklist to support the medical assessment of a wound patient. Digital checklists often are categorised as medical devices as they can support the clinical decision making. In chapter 4.2 medical device regulation is explained followed by product development process description in chapter 4.4. Chapter 4.3 explains the basics of usability; a crucial part of any medical device development.

4.1 Checklists in Health Care

Checklists are frequently used in health care, for example during surgical procedures. One of the first ground-breaking implementations of checklists was for central line cannulation at Johns Hopkins. The checklist was developed to decrease the number of infections related to the procedure. The checklist constituted of five items, which were identified based on research as affecting the most to the risk of infections. After implementing the checklist at the intensive care unit, the number of infections was decreased substantially, thus providing evidence of the benefits of checklists. Later, it has been shown that the use of checklists can reduce surgical morbidity and mortality. However, implementation of checklists should be supported by operational change management to ensure long-term adoption. (Shaw, Ramachandra, Lucas & Robinson 2011, 6-7.)

A checklist provides a quick and on-point tool for clinical practice while including all relevant items required for that particular situation. It provides a mean to easily implement clinical guidelines to practice, thus ensuring evidence-based approach is utilised in the care. (Snyder et al. 2019, S30.) For example, the World Health Organization has published a surgical safety checklist in 2008 to improve patient safety in surgical procedures. The usage of checklists has proven to promote patient safety. Research done with wound patients undergoing surgical procedure reported changes in patient care in

nearly 50% of cases due to usage of checklist. (Myers, Gilmore, Powers, Kim & Attinger 2015, 848-849, 851.)

Regardless of the ability to decrease errors in medical settings, usage of checklists has caused some negative feedback as well. Concerns raised include the design, as checklists are oftentimes static paper forms which does not answer to the dynamic health care setting. Paper forms cannot be transformed to electronic medical records, which hinders the integration of information. To solve such issues, digitisation of checklists has been attempted and recorded in research. Digital checklists can enable improved usability, adaptation of dynamic processes and support for decision-making process. (Sarcevic, Rosen, Kulp, Marsic & Burd 2016, 33-34.)

Implementation of checklists does require motivation from the professionals and use of checklists should be effective in order to be beneficial (Shaw, Ramachandra, Lucas & Robinson 2011, 7). Better usability can engage users to the service and improve the productivity as time is not lost on using complicated and non-logical digital tools (Nielsen 2012).

4.2 Medical Device Regulation

Medical device is defined as any product including software, which can be used for medical purposes such as diagnosis, prevention, monitoring, prediction, prognosis, treatment of alleviation of disease, injury, or disability. The development of medical devices is governed by EU regulation in order to ensure the safety and efficacy of the devices. The device manufacturer is responsible to validate the device's safety, performance, and its compliance to intended purpose before the device is put to market. This includes the clinical validation, risk management system and post-market clinical follow-up. The process must be documented in accordance with the regulation, and it continues throughout the life cycle of the device. In order to achieve the required actions accordingly, the manufacturer must establish a quality management system. When a device is developed according to the regulation, it will be marked with CE

marking, which indicates the conformity. (Regulation (EU) on medical devices 2017/745, articles 2, 5, 10.)

Part of the quality system, the clinical evaluation is defined as a continuous and planned process of collecting and analysing clinical evidence related to the device ensuring the safety, level of performance and realization of clinical benefits during the intended usage of the device. The manufacturer is thus obliged to provide appropriate and sufficient clinical evidence to present the conformity of the device depending on the characteristics of, risks related to and intended purpose of the device. The level of evidence, referring to the quality and amount must be determined and justified by the manufacturer. (Medical Device Coordination Group 2020, 7, 9-10.)

Three main aspects should be covered by the clinical evidence: valid clinical association, and technical and clinical performance. Valid clinical association refers to the device having a correspondence to a physiological or clinical condition or clinical parameter. The association can be evidenced by a literature research, guidelines or clinical investigations done by the manufacturer. The technical performance refers to how consistent, reliable, and accurate the device is with real-world data. Testing is one manner of establishing the technical performance affirmation. The device specifications should relate to user requirements and intended usage. The clinical performance refers that the device provides clinically sound output with regards to the intended medical purpose. The manufacturer should test the device in all environments, user groups, and in each target population and intended uses. (Medical Device Coordination Group 2020, 10-13.)

The clinical evaluation is concluded with a benefit-risk analysis to determine the possible risks and benefits related to the usage of the device for the intended purpose. The clinical evaluation, as stated earlier, should continue throughout the life cycle of the device through any data collected during the usage of the device, such as end-user feedback, new research results, and performance data. (Medical Device Coordination Group 2020, 15-16; Regulation (EU) on medical devices 2017/745, article 2.) Post-market follow-up can additionally reveal new clinical benefits, which have not been identified in the premarket phase (Wilkinson & van Boxtel 2020, 616).

4.3 Usability

Usability is defined in literature as “extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” (ISO 9241-210 2010) or “a quality attribute that assesses how easy user interfaces are to use” (Nielsen 2012). Usability can determine whether a user engages to a system. Together with utility; whether a system actually provides the features required, they form the usefulness of the system. Without good utility even a perfect usability cannot engage a user, whereas poor usability disrupts attempts to perform tasks utility enables. Thus, a useful system can engage users, which in turn can lead to increase in profits, registered users, or improvements in any other key performance indicator set for the system. (Nielsen 2012.)

When considering usability in terms of medical devices, it is as important as with any other system, or even more so as medical devices impact the quality and safety of care directly. To ensure that the medical device can be used according to its intentional use, usability plays a crucial role. Certain level of usability is required from medical devices before they can be launched into production. Usability testing is advised to be executed early in the development process and continue throughout the process. In the beginning the planning should be based on user needs, and towards the end usability testing ensures that the user requirements are met. In addition to usability testing, other approaches to improve usability of a medical device can be utilised, such as prototyping, collecting user requirements and using personas and scenarios to ensure mutual understanding between the developer and the user. One applicable method of usability evaluation is end-user interviews. (Bitkina, Kim & Park 2020; 3-6, 8.)

Nielsen (2012) identifies five quality factors which determine what usability is: efficiency, satisfaction, errors, learnability, and memorability. Efficiency refers to how easy it is for users to perform the required task after they have familiarised themselves with the design. Satisfaction refers how users perceive the pleasantness of the product or service. Errors relate to errors users make while performing the task, together with the severity of errors made and how easy it is to recover from such errors. Learnability

refers to the easiness of performing basic tasks during the first trial. Lastly, memorability refers to ability to memorise usage after a period of not using the system.

Another classification for usability dimensions has been developed by Whitney Quesenbery (2004, 5), called the 5Es: effective, efficient, engaging, error tolerant and easy to learn. These dimensions have similarities to Nielsen's quality factors. Effective in Quesenbery's classification refers to the usefulness of the product and whether it helps users to achieve goals. Efficient relates to the speed of work being done; whether the quantitative time for performing a task or more subjective measure of task requiring too many clicks. Engaging refers to pleasantness and satisfying qualities of the product. Error prevention and error recovery qualities are related to error tolerance dimension. Easy to learn relates to supportive qualities for either initial orientation or in-depth learning. (Quesenbery 2004, 5-6.) These two different classifications, Nielsen's and Quesenbery's, can be seen to intertwine and complement each other.

Effectiveness and efficiency answer to the user's requirement of accurately and quickly achieving the goal for using the product. Thus, the product should improve the current way of operating. However, it has been described in the literature that the most important measure for usability is satisfaction or engaging from the 5Es. It answers the question whether the user is satisfied with the product or if using the product is pleasing for the user. Satisfaction is purely users' subjectively reported measure, which describes the desirability of the product. Meeting users' wishes for satisfaction can determine if users will agree or resist using the product. Problems in for example effectiveness or efficiency can be averted if the desirability factor is achieved with users. (Barnum 2011, 11-14.) Satisfaction can be collected in qualitative form in users' comments during usability testing. Such comments can for example be users' verbalisations and reactions during the testing. In addition, follow-up discussions can include topics relating to satisfaction, such as asking the best and the worst features of the product. (Geisen & Romano 2017.)

Usability testing is defined by Barnum (2011, 13) as "the activity that focuses on observing users working with a product, performing tasks that are real and meaningful to

them". Usability testing aims to discover what users do and what they do not do. Usability testing provides insights whether the product meets the requirements of the users. Testing enables to collect data on users' perceptions, what they wish from the product and whether the product supports users in reaching their goals. Thus, testing focuses on the product, not on the tester. Usability testing can be executed as small, informal studies or larger, more formal manner. Smaller testing is quicker and less expensive, whereas the larger testing enables statistical data collection and provides better insights for complex products. (Barnum 2011, 10, 17-18; 21-22.)

4.4 Symptom Navigator Development in HUS IT Management

Symptom navigator development in HUS IT Management follows internal innovation process guidelines and digital service life cycle model, while implementing medical device regulation and legislation. When a need for service process digitalisation has been identified during the innovation process, the process for product development is initiated. A product owner is named, who oversees the development process. The process can be viewed to construct of three stages, each of which lead to a formal review. Formal reviews relate to medical device development; however, informal reviews can be held when product is not a medical device. The reviews ensure that product development follows the regulation, conform to the quality system, and meet the requirements set.

The product owner together with clinical professionals define the preliminary intended purpose for the product. The intended purpose guides the planning of the product requirements and focuses the risk management. The product owner is responsible for reserving resources for product development, whereas the clinic responsible for the medical content ensures that required resources for medical expertise are available in the development team. The development team finalise the intended purpose for the product, plans the product requirements and cost-benefit analysis and initiates risk management.

According to the intended purpose, product requirements and risk analysis, the product is evaluated whether it is subject to medical device regulation. If it is, a formal review (design input review, DIR) is held after the planning has been completed by reviewing the required planning documentation. The review ensures that the product requirements are comprehensive and can be validated, that implementation planning is realistic, that product risks are acceptable compared to the benefits, that the economical and clinical benefits outweigh the cost of development and that the clinic is committed to the product maintenance throughout the product lifecycle.

After the review the development team can proceed in actual product development according to the implementation plans. Agile methods, such as Scrum and Kanban are utilised in the product development. Design Output Review (DOR) ensures that the development has been done according to the planning, that required documentation is done and that product implementation to test and production environment is ready. During the review it is established whether the product development process can proceed to verification and validation.

Verification ensures that the product performs technically as planned. It includes comprehensive regression testing. Validation ensures that the product provides the clinical benefits it was planned to achieve. During validation the clinical evaluation is performed to ensure that product conforms with the requirements in conventional circumstances. The last review during the product development phase, Design Release Review (DRR), goes through the verification, validation and clinical evaluation documentation and other related release documentation. During the DRR, a decision is made whether the product is ready to be released in production. A Declaration of Conformity and a formal notification is made for the responsible authority Fimea. (HUS Tietohallinto 2021.)

5 RESEARCH METHODOLOGY

Chapter 5 represent the research methodology for this particular research. It covers the type of the research (chapter 5.1), data collection methods (chapter 5.2), data handling and ethical considerations (chapter 5.3) as well as the data analysis (chapter 5.4). It justifies the use of selected methodology for the purpose of this research.

5.1 Case Study

This research is case study research. A case study focuses on one particular phenomenon. It is often recommended to choose a case study approach if research questions begin with what, how and why, if there are only few empirical studies made, if focus of the research is a real-life phenomenon and if the researcher has little control over the phenomenon. What is important is that the case can be clearly outlined from other contexts. (Eriksson & Koistinen 2014, 4-6.)

A case study can focus for example on an organisation, a project, a group, or a process. The aim is to build a cohesive and versatile description of the case through a holistic approach. Various sources of data are often combined to achieve a broad representation of the case, such as observation, interviews, and written documentation. A case study does not aim to achieve generalisations, instead it is considered that the precise description can provide new insights on the case and the knowledge achieved could be applied to other circumstances. (Vuori a.)

This research represents a case study as it focuses on a particular development project: the Wound Navigator. It focuses on the usability of the device and does not aim for generalisations. It rather aims to describe an example of how validation and clinical evaluation activities could be performed in the context of particular organisation and its quality management system.

5.2 Data Collection

The data collection was executed in two parts. First part represented the validation in the medical device product development process, and it was conducted as an end-user testing. The nine testers were collected from two groups: medical students, and doctors working in HUS and health centres in Uusimaa region. These groups represent the end-users for the Wound Navigator solution. The end-user testing took place at either testers' workplace or via digital channel, (Microsoft Teams) depending on the tester and current governmental COVID-19 pandemic recommendations. The researcher performed as the interviewer during the data collection.

Testers were given seven fictional patient cases representing typical wound patients, which they evaluated based on their clinical knowledge. These fictional patient cases represented tasks which the testers were required to perform for usability testing. Tasks enable to follow how testers achieve to complete the task. Without such tasks, testers would wander around the interface without any set goal, thus making it impossible to establish possible usage patterns. It might additionally hide any recurrent problems in the product when it would not be possible to compare the use among and between testers. (Barnum 2011, 19.) The fictional patient cases covered different decision trees of the Wound Navigator to ensure comprehensive testing procedure.

The patient cases were written following the method for key feature problems (KFP), which are generally used for clinical decision-making skill testing. Key feature problem method allows to identify the critical issues related to clinical decision-making and represents a validated measure for diagnostic accuracy. (Farmer & Page 2005, 1188; Page & Bordage 1995, 109-110.) Key features concentrate on phases where errors are most likely to happen and they represent the known issues with regards diagnosis and management (Page, Bordage & Allen 1995, 195). Thus, for each fictional patient case, there were a set of key features which represented the critical issues required for understanding the aetiology of the wound and deciding for follow-up procedures.

The patient cases included information regarding the history and current situation together with a picture of the wound. Testers could ask for more information regarding the patient during the testing. Testers stated their conclusions and defined the follow-up procedures which were recorded and analysed according to the predefined key features. After going through the seven patient cases, testers used Wound Navigator and went through the cases again. The action suggestions given by Wound Navigator were recorded and again analysed according to the key features. The results were then compared and evaluated for differences. Differences could have been for example the number of identified key features, differences in follow-up procedures or differences in perceived aetiology of the wound. What was important to notice is that in this research the KFP method was not used to evaluate the clinical skills of the testers. It was used only to provide a framework according to which the possible differences between clinical decision-making without and with the Wound Navigator were compared.

In addition to fictional patient case evaluation without and with Wound Navigator, testers were interviewed regarding the usability of Wound Navigator as part of clinical work. The interviews were semi-structured, in order to be able to clarify and deepen the discussion on possible issues raised during the interviews. The interview topics are presented in Appendix 2. The basis of the interview was three usability dimensions by Quesenbery, effectiveness, efficiency, and engagement, which are presented in chapter 4.3. These three dimensions were selected as they are considered to be the most important for the overall usability (Barnum 2011, 11). It should be noted, that even though there are fixed questions set in the Appendix 2, the interviews were executed as semi-structured method.

Semi-structured interview method additionally allows flexibility as the interviewer can change the order of the questions. (Tuomi & Sarajärvi 2018.) Semi-structured interviews can be utilised when some background information is already known but further knowledge is required. Through semi-structured interviews it is possible to reveal issues which were unidentified. On the other hand, semi-structured interviews enable the possibility to redirect discussion back to the topics of interest if conversation steers away from the topics. While performing a semi-structured interview, the interviewer

must proceed cautiously in order to avoid affecting the interviewee's answers. (Wilson 2014; 24, 26, 28.)

The interviews were recorded, and transcription was done for the recordings to enable data analysis. The entire end-user testing was observed when possible, and any findings relating to the use of Wound Navigator were noted and included in the data collection. Observation was not possible during some of the interviews which were done remotely due to technical issues.

The second part of data collection focused on collecting insights to complement clinical evaluation in the medical device product development process. The representatives of Finnish Medical Association's Committee for Special Competence in Wound Management were contacted through email to collect expert statements on the contents, validity, and usefulness of Wound Navigator. The representatives were sent the visual flow charts of Wound Navigator and access to pilot version of Wound Navigator together with a link to an electronic questionnaire with open-ended questions regarding the clinical accuracy and usefulness of Wound Navigator through email. The questionnaire is presented as Appendix 3. Based on their observations and evaluation of the provided material they drew up their expert statements to the electronic questionnaire.

Expert statements are used in various situations in health care. For example, consultation and expert statements represent an integral part of the process of developing Current Care Guidelines. By collecting expert statements, it is ensured that viewpoints of different health care operators are taken into notice in Current Care Guidelines. (Honkanen, Jousimaa, Komulainen, Kunnamo & Sipilä 2021.) Expert statements have additionally been used in HUS IT Management product development process before. For a medical device developed for acute medical situations, expert statements were used as the method for clinical evaluation.

Expert interviews are used as a research methodology to acquire information experts possess on the research subject. The aim is to produce new information by utilising expert knowledge. Expert interviews can be performed in a variety of ways according to the research topic and research questions. (Alastalo, Åkerman & Vaittinen 2017,

184-185, 187.) In this research however, due to experts' time constraints, expert statements were collected as written reports through online questionnaire instead of interviews.

5.3 Data Handling and Ethical Considerations

In the research the guidelines for responsible conduct of research (the RCR guidelines) published by the Finnish Advisory Board on Research Integrity (Tutkimuseettinen neuvottelukunta 2013) were followed. A research permit was be applied from each organisation separately (HUS, Vantaa health services for Tikkurila health centre and Keusote). Participation to the research was voluntary and each research participant was asked to give consent for participation and handling of personal data. Template for the consent is presented in Appendix 1.

The data collected was handled with confidentiality and according to the General Data Protection Regulation. All patient cases used during the research were fictional, which ensured that no sensitive or personal data was handled. The data collected was not connected to the personal data of the testers.

5.4 Data Analysis

The data collected during data collection phase was first collected in one Excel file, where the findings were coded according to the different usability domains effectiveness, efficiency, and engagement, together with utility and usefulness. These domains and concepts represented the themes for analysis. Following the thematisation, the findings were analysed using qualitative content analysis by connecting the findings to the theory. The focus on qualitative content analysis is which aspects, subjects and themes the data describes. It highlights the issues interviewees discuss, or subjects raised in documents. Qualitative content analysis can be used to analyse written text, recorded discussion, interviews, sounds and pictures. During the analysis, the data is organised in a concise way, while retaining the information included in the data. The key is to perform the analysis systematically; all data is analysed according to same

framework. This data coding is followed by drafting conclusions, which present aspects of interest in more general level. (Vuori b.) The analysis is presented in the following chapters.

6 RESULTS

This chapter presents the findings of the data collection described earlier. Firstly, end-user tester profile is described to establish the base for the analysis. Secondly, it is described how the Wound Navigator affects the clinical decision-making process based on the end-user testing, approaching the subject from effectiveness dimension of usability. In chapter 6.3 the usability of the Wound Navigator is evaluated from efficiency and engagement dimension point of view. Lastly, the focus is shifted to expert statements, which provided insights for clinical evaluation of the Wound Navigator.

6.1 End-User Tester Profile

End-user tester profile was established based on the answers for the background and digital tools and checklists question topics. These topics are listed in part two, sections A and B of the Appendix 2. Testers participating in the end-user testing represented the intended user group for the device. Majority of testers were Licentiates of Medicine, while few had completed Bachelor of Medicine degree. Licentiates were working in health care centres and had gained few years of experience in clinical work. Three testers had had internship in dermatology ward, which had included some wound management experiences. Rest of the testers had treated some wound patients during their work career but did not have any specialised education on wound management.

The testers had had some experiences in using digital tools in their clinical work. Tools they listed mainly consisted of web pages, which include guidelines and instructions, such as Terveysportti and Health Village PRO. Some testers reported they have used

tools, which were developed for one particular issue, such as for PEF-measurement analysis or anticoagulation calculations. In addition, some testers reported to have used tools provided by their employer, such as remote appointment software and Microsoft Teams.

Utilising checklists, whether digital or in paper format was not widely popular among the testers. Only two testers reported to have used checklists. However, all testers considered that digital checklists could be useful in clinical work. Especially in more complex situations, for example with untypical wound patients, they considered a checklist would provide additional support in the decision-making process. Several testers emphasised, that in order to use digital checklists, they should be easily accessible. For example, tester mentioned that "I would use digital checklists if they were readily available and quick and clear to use. Effortless."

6.2 Wound Navigator Supporting Clinical Decision-Making

The first usability dimension which was on focus in the analysis, was effectiveness. Effectiveness addresses whether the user is able to complete the assigned tasks with the service (Quesenbery 2004, 5). The aim of the Wound Navigator is to support the clinical decision-making process. Thus, in order to achieve effectiveness usability dimension with the Wound Navigator, it should provide means to support clinical decision-making.

Effectiveness was evaluated by patient case evaluation with key feature problems as explained in chapter 5.2. During the data analysis, the findings from the patient case evaluation was complemented with the semi-structured interview answers which related to the clinical decision-making process. In the patient case evaluation, testers were given seven fictional patient cases, which included picture(s) of the wound and some medical history and wound details. When testers evaluated these patient cases, they could ask for more details, for example regarding ankle brachial index (ABI). If they did not ask for more details, such information was not provided automatically. The seven patient cases represented typical wound patients:

1. Atypical lower limb wound with wound infection (pyoderma gangrenosum related to Crohn's disease).
2. Lower limb wound related to swelling in the limb.
3. Lower limb wound related to ischemia and swelling.
4. Ischemic pressure wound in lower limb.
5. Diabetic and neuropathic lower limb wound.
6. Pressure wound in buttocks area.
7. Post-operative atypical (pyoderma gangrenosum) wound in upper limb.

Testers were not able to use any reference material or support tools while evaluating the fictional patient cases, thus they needed to rely on their previous experiences in treating wound patients. This way testing was not influenced by testers' abilities to find information from different sources.

Testers were more confident when evaluating patient cases 2-5, which was represented as ease in determining the follow-up procedures and possible aetiology. Ease represented as swiftness of deciding on the procedures and naming the possible aetiology. For few test cases verbal expressions made it clear that tester had no trouble in identifying the wound; tester for example stated, "I know this, I know this.", while another tester verbalised: "I know what is behind this, I know what is being sought here…". In addition, for more familiar cases, testers often reported possible diagnoses and presented assurance in their decision.

Cases 1-5 were more typical lower limb wounds, which represent majority of wound cases seen at primary health care setting. Cases two, six and seven were clearly more difficult to assess. Case 7 caused most amount of uncertainty among testers, and majority of the testers reported that they did not have any idea what the aetiology of the wound could be. However, most were able to identify recommended procedure (biopsy). Testers reported for example that "I don't know about the aetiology" and "[the wound] possibly from the operation, cannot really say that well". One tester was not able select any follow-up procedures for case 7. Time used to evaluate the patient cases did not clearly correlate with the difficultness of the case, as some more difficult cases took less time to evaluate compared to cases which tester felt more comfortable with.

This might be explained by having clear idea how to proceed with cases which were more familiar.

After evaluating the seven patient cases testers went through same cases again with the help of the Wound Navigator. They answered the questions in the Wound Navigator and received a summary of their answers and procedure recommendations for each patient case. All testers received valid instructions and procedure recommendations for each patient case when using the Wound Navigator. The validity of recommendations was established through covering the key feature problems set for each patient case. The results received with the Wound Navigator were compared with the evaluations made without the Wound Navigator. The comparison was made with the help of key feature problems by comparing which key features were mentioned by the testers without the Wound Navigator and which key features were covered by the results received from the Wound Navigator.

In Table 1 the comparison is presented as summary, and markings used are explained below. The quantitative summary is for visualisation purposes.

- w/o WN = Without the Wound Navigator
    - ? = The tester mentioned some of the key features, but did not cover them all
    - X = The tester mentioned all key features
    - - = The tester did not mention any of the key features
- with WN = With the Wound Navigator
    - X = The tester received correct conclusion and procedure recommendations from the Wound Navigator
    - X+ = The tester received correct conclusion and procedure recommendations, but there were additional conclusions received from the Wound Navigator

Table 1. Summary of patient case evaluation comparison.

Tester	Test case 1		Test case 2		Test case 3		Test case 4		Test case 5		Test case 6		Test case 7	
	w/o WN	with WN	w/o WN	with WN	w/o WN	with WN	w/o WN	with WN	w/o WN	with WN	w/o WN	with WN	w/o WN	with WN
Tester A	?	X	X	X	X	X+	X	X+	X	X	X	X+	-	X+
Tester B	X	X	X	X+	X	X+	X	X	X	X+	X	X	?	X
Tester C	?	X	X	X+	X	X+	X	X+	X	X+	X	X+	-	X+
Tester D	X	X	X	X+	X	X+	X	X+	X	X+	X	X+	X	X+
Tester E	-	X	X	X	X	X+	X	X	?	X+	X	X+	?	X
Tester F	-	X	-	X+	X	X+	-	X+	X	X+	-	X+	?	X+
Tester G	X	X	X	X+	X	X	X	X	X	X+	-	X+	X	X
Tester H	X	X	X	X+	X	X	X	X	X	X+	?	X+	?	X
Tester I	X	X	X	X	X	X+	?	X	X	X+	-	X+	?	X+

The effectiveness dimension of usability measures whether tasks given were successfully completed (Quesenbery 2004, 5). With Wound Navigator, all testers were able to go through each patient case evaluation. They were able to proceed from one question to the next without issues, and complete the question sets for each patient case. After the questions, testers received valid conclusion and procedure recommendations for each patient case. They were able to receive conclusion and procedure recommendations also for the patient cases they were not able to resolve without the Wound Navigator as presented in Table 1.

The conclusions given by the Wound Navigator depends on the answers the user has given. Thus, if user selects for example that there are clinical infection signs and atypical wound appearance, the Wound Navigator will include both in the conclusion. During testing this situation became apparent, because testers were not sure what to answer to some questions in the Navigator (market as X+ in Table 1). This was the case for example for question regarding wound infection, atypical wound signs or questions which had medical terms testers were not familiar with. Regardless of receiving several possible conclusions from the Wound Navigator, majority of testers considered that it helped them to select and narrow down possible follow-up procedures especially in the more complex cases. For example, one tester mentioned when discussing the benefits of the Wound Navigator, that it “provided additional info”, and other mentioned, that it “could confirm own decision-making or broaden it if something was left unnoticed”.

As mentioned above, it was pointed out by the testers and also observed during end-user testing, that some of the medical terms and descriptions used in the Wound Navigator were not familiar. They can be clear to the specialists, but for end-users they

might be completely unknown. Examples of these were purple rim around the wound, as it was not defined more precisely, sinus pilonidalis, which might not be familiar term, and wheelchair not being considered to be a medical device. As seen during the testing that the Wound Navigator provided multiple conclusions and procedure recommendations, such unclear concepts can affect the effectiveness of the device. This can be evident if user feels confused by the different conclusion options, or the user might not be able to go through the questions if one does not understand what is asked. This would hinder user from completing the task, thus affecting the effectiveness dimension of usability.

Another issue which could weaken the effectiveness dimension related to the concepts used was observed during the testing. Testers seemed to consider that the wound had signs of infection even when there were no clinical infection signs evident. This was caused by vague definition of the clinical infection signs. This was not mentioned by the testers as something to be improved, but as it clearly was observed on several occasions during the testing, it was evident that the question needed to be clarified to promote the usability of the device.

Some questions from the Wound Navigator prompted the testers to ask for details they did not notice to ask when evaluating the case without the Wound Navigator. Such questions included ABI levels or suitability of footwear. Testers verbalised this during the patient case evaluation with the Wound Navigator by saying: “Oops, I didn’t remember to check this in the first evaluation round.” and “I completely forgot to consider the footwear.”. Several testers reported as the Wound Navigator’s benefits that it brought structure to the patient assessment, which can be hard especially in more complex wounds. They felt that it covered variety of issues which can affect the wound; some of which they would not necessarily have noticed themselves. This was described by the testers for example “…it asks really special issues as well, things which would not be considered otherwise.”, “when evaluating the patient myself, it is not necessary that structured…” and “…especially when there is more problematic case, it brings good structure…”.

6.3 Efficiency and Engagement of Wound Navigator

The usability of the Wound Navigator was studied not only from effectiveness dimension point of view, but also from efficiency and engagement dimensions point of view. Efficiency relates to how quickly the work can be done, whereas engagement relates to the pleasantness of using the device (Quesenbery 2004, 5). Efficiency was partly studied in the patient case evaluation described in chapter 6.2, and complemented with the semi-structured interview answers, whereas the engagement dimension was covered by interview answers. Observation findings were integrated in the analysis.

During the end-user testing, the testers pointed out that the user interface was clear to use. For example, testers mentioned, that "the Wound Navigator worked smoothly and was clear" and "It was clear and did not have too many options to choose from". Not having too many options or in-depth questions made it faster to use. In addition, one tester mentioned that there was no need for operational instructions. Similar findings were made while observing the testing. The testers did not stop to think how to proceed, and they did not ask for instructions during testing how to use the Navigator. Clear interface promotes the efficiency, as the user does not have to spend time in figuring out how the device functions. Additionally, time is saved if the user does not need to look for instructions.

Testers pointed out couple issues relating the efficiency of the Wound Navigator during the interview. There were two ideas how to improve: to combine several questions in one view, and to present some of the procedure recommendations to the Navigator itself. In the tested version of the Wound Navigator, the questions were presented to the user one by one, thus when user answers one question, the next will be shown to the user. Combining several questions in one view would decrease the number of clicks user makes. This would speed up the answering, thus improving the efficiency of the device.

The procedure recommendations are given in the Wound Navigator in two ways: short recommendations directly after the user has answered all questions and longer, more comprehensive instructions are given in a separate pdf document, which the user can

open and download when necessary. Testers reported that they would wished that some of the additional instructions could have been added to the Navigator from the pdf document. This would improve the efficiency of the Navigator, as the user would not need to open the pdf document. Another issue relating to the pdf recommendations related also to the number of clicks. This matter was raised through observation. Testers needed to make several mouse clicks to open the pdf procedure recommendations, again affecting the efficiency.

When engaging dimension of usability was explored from the data collected, several matters were revealed. All testers reported they could use the Wound Navigator at clinical work to assist in wound patient assessment. They for example described that "…it is like a game!", "its quite a bomb, in a positive way." and "…nice, compact tool…". Positive notions received from the users indicates that the user interface of the Navigator has aroused positive feelings among the testers. Positive feelings promote the engagement to the service. Several testers were eager to start using the Wound Navigator in their clinical work as soon as possible. Notion that the Navigator resembles a game can mean that user feels engaged to the service. Gamification is commonly used in digital service design to increase the engagement of users (Interaction Design Foundation).

In addition, the finding mentioned above in efficiency-section, that the user interface was described as clear can be perceived to relate to the engaging dimension as well. Easy and pleasurable user interface promotes engagement and satisfaction to the device. Several users emphasised that the Wound Navigator would be used especially with more complex cases as it provides "concrete instructions and simple questions". For good features of the Wound Navigator the testers mentioned that the recommendations were clear and concise. This was especially important for the patient cases which were more complex, with which many of testers struggled to identify the cause of the wound and follow-up procedures. The procedure recommendations gave assurance how to handle such difficult wounds, and verification that for example reference to specialist can and should be done early in the process for some cases. Such assurance can promote the engagement to the device.

6.4 Clinical Accuracy and Usefulness of the Wound Navigator

The expert statements collected from professionals served as the base for evaluation of clinical accuracy and usefulness. The contents of the Wound Navigator include topics from various medical specialties, such as plastic surgery, dermatology, and internal medicine. Thus, it was crucial to collect feedback from physicians who are specialised into those medical specialties. The expert statements were collected and analysed during the data analysis similarly than end-user testing, but findings are reported separately from the end-user testing (chapters 6.1-6.3). In this way, it is easier to differentiate the views of intended end-users from wound management professionals, who do not represent the end-users for the Wound Navigator. Utility formed the background for the clinical accuracy analysis, as it refers whether the device actually provides the features required. Utility related questions are presented in Appendix 3 as fourth and fifth questions. Other questions on Appendix 3 relate to the usability or the Wound Navigator as perceived by the wound management experts.

The experts reviewed the Wound Navigator flow charts in pdf format and were able to test the actual tool in test environment. Experts decided themselves how comprehensively they tested the Navigator, but they were instructed to cover wounds typical for their medical speciality. Overall, the expert statements agreed that the flow charts of the Wound Navigator were clinically accurate. For example, one expert mentioned that "[flowcharts] are comprehensive enough for primary health care" and another mentioned, that "tested 5-6 cases, no issues noticed". With regards to the procedure recommendations, the opinions of the experts were not unanimous. One responded stated that recommendations are clear and appropriate. Another respondent noted that the Navigator felt too simplified for clinical setting. This might be due to issue of narrowing the content in order to improve the usability of the Navigator, which was decided upon during the development of the Navigator. Wider content would have increased the time required to fill in the Navigator, which would have made it less usable in clinical setting. As pointed out in previous chapter, quick use is crucial metric for usability. Thus, the development team considered that the content was covering all critical issues and aspects related to wound management at primary health care setting.

Based on the expert statements, the utility of the Wound Navigator can be evaluated to be sufficient for primary health care use.

From usability point of view, the experts pointed out that the interface required scrolling, which can affect the efficiency dimension of usability. Scrolling can be time consuming, as it requires the user to move and click the mouse. In addition, it was noted that changing the answers to previous questions should be possible. This again affects the efficiency, if user needs to start from beginning if they need to change the answer to previous questions. Positive features mentioned by the experts were unambiguous answer possibilities, and ease and quickness of use. These relate to efficiency dimension and were similar with the end-user opinions.

Few development ideas were pointed out in the expert statements. These included changing some terms to more accurate synonyms, such as “sugar levels” to be changed to “blood glucose levels”. Another development idea regarded the wording of the procedure recommendations. Especially the instructions concerning wound infection were elaborated based on the expert statements.

Usefulness of a system is compiled from the usability and utility; usability aims to engage the user whereas utility aims to provide features required (Nielsen 2012). Usefulness cannot thus be achieved with one without the other. Experts were asked about the usefulness of the Wound Navigator in their statements. The opinions were divided between the respondents. The Wound Navigator was considered to be useful in primary health care setting, which is the target audience for the Navigator. However, in specialised medical care setting the Navigator was not considered a useful tool by the experts.

7 DISCUSSION

This chapter connects the theoretical background and the results presented in previous chapter. The aim is to venture deeper to the analysis of the data collected. In chapter 7.1 thought is focused on digital checklists in clinical decision-making setting. Next, the key components of usability of digital checklists are discussed in chapter 7.2. Chapter 7.3 concludes the discussion with findings related to validation activities and clinical evaluation of Symptom Navigator in HUS IT Management.

7.1 Digital Checklists in Clinical Decision-Making

Checklists have been used in health care frequently and research has shown that using checklists can decrease adverse effects and improve quality of care (Shaw, Ramachandra, Lucas & Robinson 2011, 6-7; Snyder et al. 2019, S30). Digital checklists have been shown to support clinical decision-making and improve usability of checklists (Sarcevic, Rosen, Kulp, Marsic & Burd 2016, 33). In this research, it was studied how a digital wound management checklist can support the clinical decision-making.

Based on the findings from this research, digital wound management checklist can have a positive impact on the clinical decision-making. Two scenarios clearly stood out from the testers feedback:

- Complex or otherwise untypical wound patient assessment.
- Unexperienced physician (long time since treating a wound patient or less experience in treating wound patients), especially in primary health care.

Digital wound management checklist can provide structure to the patient assessment as it prompts the user to go through required questions to produce procedure recommendations. The questions are evidence-based and follow predetermined decision trees. Thus, it can remind the user from various aspects which can affect the wound. The user can follow the questions when evaluating the patient case to ensure that all

relevant factors are taken into account in the decision-making. This is especially helpful in complex patient cases, where there can be multiple comorbidities affecting the wound.

Another benefit of digital wound management checklist in clinical decision-making is that it can either enforce or broaden the clinical decision-making. As it provides procedure recommendations, the user can compare one's own reasoning to the results received from the Navigator. The physician is always responsible for the decision-making, but using the digital checklist, the procedure recommendations can be used to ensure all recommended procedures are done.

It is important to note however, that the digital wound management checklist should be used only in the clinical setting defined in its intended use, which is the primary health care. It was established in the research, that the content of the checklist is too narrow for specialised medical care context. Thus, the user should understand the context where to use the checklist and where it should not be used. This should be advised to the user clearly.

The testers reported that they had not used checklists widely in their clinical work. However, they did report that checklists could support clinical work. Testers did report that they have used some digital tools in their work. Still, it can be considered surprising how few digital tools have been used, as testers represented the age group who can be considered as digital native. Based on the findings in this research, it seems that there is an unmet need for digital checklists, especially as literature has shown that use of checklists can decrease adverse effects in health care.

7.2 Usability of Digital Checklists

Usability is defined in literature as "extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (ISO 9241-210 2010). In this research, usa-

bility of the digital wound management checklist was studied from the three key dimensions: efficiency, effectiveness, and engagement. Implementation of checklists requires motivation from the professionals and use of checklists should be effective in order to be beneficial (Shaw, Ramachandra, Lucas & Robinson 2011, 7). Better usability can engage users to the service and improve the productivity as time is not lost on using complicated and non-logical digital tools (Nielsen 2012).

The testers underlined the importance of ease of use during the interviews, and prominent themes which were evident were quickness and clarity. Each tester emphasised that they would use digital checklists if they were quick and easy to use and readily available. Testers considered that the wound management checklist had clear user interface, which supported the usability. To further improve the efficiency dimension, the number of mouse clicks required was noted as a development matter for the device. It was mentioned by the testers that lack of time and resources can hinder or even prevent the use of digital tools in clinical setting, however useful they might be. The efficiency dimension of usability was thus considered critical. Digital checklists must not only provide the features needed (utility), but emphasis must be put to the time resource required to use them. Too complex and time-consuming tools are not usable in the current health care setting. There is a great need to produce tools which save time rather than spend it.

Engagement dimension has been considered the most important factor in usability. Users expect good usability and if those expectations are not met, users will not be engaged to the device. (Barnum 2011, 12.) In this research, engagement was studied from end-user point of view. End-users gave positive feedback during the testing. They considered that the wound management checklist is a tool that they would use in their work. They even presented eagerness to begin using the checklist as soon as possible. Such findings give insight to the engaging qualities of the device. It indicates that the device has achieved to engage testers with a tool that meets their expectations. When combining the end-user testing findings in the context of the three usability dimensions, it can be concluded that it each of three usability dimensions are important for users to adopt the tool in their work routines.

The remarks given by the wound management experts regarding the usefulness of the wound management checklist was not unanimous. Especially important notion was the context dependency of the tool. Through the analysis presented in Chapter 6, utility of the Wound Navigator can be perceived to support the primary health care use; however, the wound management experts did have reservations on its usefulness in specialised medical care setting. This research underlined the importance of defining the intended use for the device to ensure that it meets the user requirements and provides accurate output. For medical devices, the manufacturer must ensure that the device provides clinically sound output with regards to the intended use by testing the device in its intended use with the intended user group. (Medical Device Coordination Group 2020, 10-13.)

7.3 Validation and Clinical Evaluation of Symptom Navigators

When developing software which is classified as medical device, the development process must follow the quality system protocols. This is to ensure the quality and safety of the software, which is particularly important in the context of health care. (Regulation (EU) on medical devices 2017/745, articles 2, 5, 10.) During this research the aim was to explore how validation and clinical evaluation, both representing the crucial parts of quality system, could be executed when developing Symptom Navigators to Health Village service platform.

Validation activities were executed as usability testing with end-user testing protocol. Usability testing is defined as "the activity that focuses on observing users working with a product, performing tasks that are real and meaningful to them". It aims to discover what users do and what they do not do, thus enabling data collection on users' perceptions, what they wish from the product and whether the product supports in reaching their goals. (Barnum 2011, 10, 13, 17-18; 21-22.) Due to the COVID-19 pandemic, majority of the testing was carried out remotely. This was not ideal as observation was limited during the remote testing situations due to technical problems during the testing. Testers had difficulties in sharing their screen, and due to time constraints, it was not possible to reschedule or otherwise solve the technical issues. Observation

nevertheless provided valuable insights on how users used the Wound Navigator; where they stopped for longer period of time, where they needed assistance to proceed, was the software intuitive to use and so on. Such use insights were not achieved during remote testing. Thus, when planning end-user testing for Symptom Navigators, face-to-face testing can provide valuable addition to interviews. Observation can reveal use issues, which could not otherwise be noticed. It can also depict how users tend to use the Navigator regardless of the user manuals or instructions. People have outstanding capability of using software in ways which was not intended by the manufacturer. Observing end-user testing can reveal such misuse, whether done intentionally or unintentionally. Thus, manufacturer can alter the software to prevent such usage, which in turn improves the quality and safety of the software.

In addition to face-to-face testing, it would be highly beneficial to set up the testing as authentic as possible. Having fictional patient cases without the patient present on the testing situation affected the reliability of the Wound Navigator testing. Testers had to rely on visual pictures, and they were not able to examine the wound similarly to what they could have done if patient was at their clinic. In addition, being able to evaluate the usability in real-life setting would have required additional testing in such situations. Organising authentic testing situation is difficult, but even a couple test cases with real patients would have improved the reliability of the testing situation. However, the COVID-19 pandemic did not allow such test scenarios at the time of the research.

Collecting expert statements to compliment clinical evaluation improved the reliability of the clinical evaluation. The contents of the Wound Navigator are quite complex with seven different decision trees and procedure recommendations covering several medical specialties. Collecting expert statements provided invaluable feedback from professionals, who have expertise in wound management. They were able to evaluate the medical accuracy, as they are familiar with the latest recommendations, best practices, and instructions of various organisations. Experts' feedback complemented the findings from end-user testing, and they pointed out different development ideas than what was collected from end-user testing. Thus, expert statements provided additional value to the clinical evaluation than what conventional literature research provided.

The approach selected for validation activities and clinical evaluation of the Wound Navigator can be considered sufficient. The process did affect slightly the overall timing of the development project, but the gains well outweigh the time resource spent. The end-user testing and expert statements enabled to collect invaluable feedback and development ideas while providing valuable insights on the usability and correctness of the Wound Navigator. This enabled to result in better quality medical device software. Based on the experiences of this research, it can be concluded that this protocol can be utilised in upcoming Symptom Navigator development projects.

Navad et al. (2021) presented, that engaging professionals to digital tools requires opportunities to influence the development and to support a positive attitude towards the tool. The tool should be easy to use, and it should support professional's work. To develop timesaving, usable and truly beneficial tools, it is crucial to involve the end-users into each stage of the development process. Involving end-users to the development process enables to understand the operational context and the unique needs of the market. End-users feedback in invaluable throughout the development process, and utilisation of service design tools, such as prototyping can bring additional benefits to the development process. Especially when developing tools, which are considered medical devices, it is paramount to understand how end-users will operate the device to ensure the safety of the device.

8 CONCLUSION

This research aimed to gain experiences and understanding how validation and clinical evaluation of a Symptom Navigator can be executed in HUS IT Management. A case study, which explored the usability of the Wound Navigator in clinical setting provided the base for this research. Through the case study understanding of the validation and clinical evaluation process was achieved and the findings provided insight to future projects.

The research project was executed during the COVID-19 pandemic, which had significant impact on the practical phase of the research. The data collection was mostly done remotely. This decreased the possibility for observation as a data collection method, as some testers were not able to share their screen. In addition, it was not possible to achieve authentic testing situation, as it was not possible to have actual patients instead of fiction patient cases in the testing situation. The number of end-users involved in the testing was limited due to the pandemic. Similarly, the unique situation caused by the pandemic affected the collection of expert statements as many professionals were relocated to other duties and resources were reallocated to treatment of COVID-19 patients.

Limited number of testers and expert statements affected the reliability of the research. However, there were similarities in the testers' answers and same themes recurred in the interviews and discussions. Being able to have actual patients instead of fictional patient cases could have provided larger scale improvements to the reliability of the research rather than increasing the number of testers. With regards to expert statements, there was not clear patterns or recurring themes apparent. Thus, the number of expert statements should have been higher, in order to be able to achieve more scalable results.

Another issue regarding the expert statements was the introduction provided for the experts regarding the Wound Navigator. It would have been more beneficial to describe the Navigator in more detail including the end-user groups. This would have enabled the experts to understand more thoroughly the context where the Navigator is intended to be used. For future, it would be beneficial to reconsider if there are better ways for collecting the expert statements than what was used in this research.

With regards to data collection and usability evaluation based on the data collection, the interview topics should have been more closely linked to the theoretical framework. This would have significantly affected the reliability of the results.

Despite of the shortcomings, this research achieved to gain knowledge how the validation and clinical evaluation can be executed for Symptom Navigators. The end-user testing and expert statements provided invaluable insights not on to the usability of the Navigator, but also how users actually use it. Such insights cannot be achieved without including the end-users in the development process. With regards to future Symptom Navigator development projects, the experiences gained from this research underlines the importance of end-user testing. Hence, end-user testing is suggested to be integrated as part of the Symptom Navigator development process at HUS IT Management, regardless of whether the developed product is classified as medical device or not. The benefits gained from end-user testing clearly outweigh the resources it takes to execute it.

Digitalisation of health care is transforming the work of professionals in clinical setting. Electronic patient records represent only the first step in the digitalisation path as physicians are faced with increasing number of digital tools and services in their everyday work. Algorithms, prediction models and AI applications are harnessed to assist, facilitate, and even to automate the decision-making processes in clinical setting. Professionals need to be able to understand how such devices operate if they wish to utilise the full potential. Physicians must additionally understand the risks such automated systems impose to their decision-making process and ultimately to their patients. Participating to the development of such tools increases the common understanding of such tools and supports the implementation to practical work.

The findings of this research were utilised in the development of the tool, as improvements were carried out iteratively. For example, explanations of medical terms were added to the Navigator. In addition, more precise descriptions were added to questions where the user should identify key visual ques, such as a purple rim around the wound. Such descriptions included net-like webbing, width of the rim and so on. Based on the observation, the wording and answer choices of some questions were unified to provide more cohesive terms and language.

8.1 Suggestion for further research

In the future, it would be beneficial to gain insights how validation and clinical evaluation has been executed for different medical devices. This can be difficult subject for research as manufacturers might not be willing to share this information if they perceive it to be part of their business secrets. However, such research could provide valuable understanding and guidance for manufacturers as well.

One important aspect when considering digitalisation of health care arose during the analysis of the interviews. How end-users find the available tools, and vice versa, how product and service providers inform possible users of the new tools. It is known that digital health care solutions cover a huge market, where new devices and tools are published daily. Still, it seems that end-users are not actively using such solutions in their daily work. Could it be that physicians are not able to find solutions which they find useful and of high quality? Integrating such solution and tools to portals which are already know and used by the target audience thus provides additional benefits for both to end-users and manufactures as well. End-users could trust that the tools provided are of high quality and reliable whereas manufacturers would be able to attract wider user group. Another way to distinguish that a tool is developed with high quality is the CE-mark.

Another aspect which could of interest for future research is how medical professionals are willing to use new digital tools and how they evaluate the quality of the tools. Do medical professionals understand for example the meaning of CE-mark and what does that means with regards to the quality of the device. As there is ever-growing supply of digital tools for medical professionals, how they can be able to pick the ones which actually are useful, safe, and reliable to use. This could even develop into business opportunity: to create a database for medical professionals of different digital tools. The database could include information regarding to what purpose the tool could be used, evaluation of its quality, who has published the tool and so on.

Lastly, one idea for future research relates to data collection methods. As stated earlier, collecting expert statements proved challenging in this research. It would be beneficial

to explore ways how to collect expert statements as part of a research. What could be the most intuitive method, and how the experts perceive the collection methods. As learned during the COVID-19 pandemic, remote data collection methods might be required more in the future, especially when considering bachelor and master level thesis.

REFERENCES

Aalto, A., Ahola, I., Hytönen, J., Paavonen, M., Palmén, O., Pääkkönen, J. & Tamminen, V. 2020. Suomen julkisen talouden kestävyys. Valtionvarainministeriön julkaisuja 2020:59.

Ahmajärvi, K. & Isoherranen, K. 2017. Kroonisten haavojen hoito perusterveydenhuollossa. Suomen Lääkärilehti 8, 524–528.

Alastalo, M., Åkerman, M. & Vaittinen, T. 2017. Asiantuntijahaastattelu. In Hyvärinen, M., Nikander, P. & Ruusuvuori, J. (Eds.), Tutkimushaastattelun käsikirja (181–197). Tampere: Vastapaino.

Allen, S. 2019. 2020 global health care outlook. Laying a foundation for the future. Deloitte Development LLC.

Antes, A. L., Dineen, K. K., Bakanas, E., Zahrli, T., Keune, J. D., Schuelke, M. J. & DuBois, J. M. 2020. Professional decision-making in medicine: Development of a new measure and preliminary evidence of validity. PLoS ONE 15(2), 1–18.

Arvonen, S. & Lehto-Trapnowski, P. 2019. Tekemisen meininki – Virtuaalisairaala 2.0 -kärkihankkeen yhteenveto. Helsinki: Helsingin ja Uudenmaan sairaanhoitopiiri.

Barnum, C. M. 2011. Usability Testing Essentials: Ready, Set… Test! Burlington: Elsevier Inc.

Bitkina, O. Vl., Kim, H. K. & Park, J. 2020. Usability and user experience of medical devices: An overview of the current state, analysis methodologies, and future challenges. International Journal of Industrial Ergonomics 76, 1–11.

Eriksson, P. & Koistinen, K. 2014. Monenlainen tapaustutkimus. Helsinki: Kuluttajatutkimuskeskus.

Farmer, E. A. & Page, G. 2005. A practical guide to assessing clinical decision-making skills using the key features approach. Medical Education 39, 1188-1194.

Garmann-Johnsen, N. F., Helmersen, M. & Eikebrokk, T. R. 2020. Employee-driven digitalization in healthcare: codesigning services that deliver. Health Policy and Technology 9, 247-254.

Garrett, J. J. 2011. The Elements of User Experience. User-Centered Design for the Web and Beyond. 2nd ed. Berkeley: New Riders.

Geisen, E. & Romano, J. 2017. Usability Testing for Survey Research. Cambridge: Elsevier Inc.

Gjellebæk, C., Svensson, A., Bjørkquist, C., Fladeby, N. & Grundén, K. 2020. Management challenges for future digitalization of healthcare services. Futures 124, 1-10.

Gottrup, F., Henneberg, E., Trangæk, R., Bækmark, N., Zøllner, K. & Sørensen, J. 2013. Point prevalence of wounds and cost impact in the acute and community setting in Denmark. Journal of Wound Care 8, 413-422.

Health Village. 2020. Mikä on Terveyskylä? Retrieved 15th April 2021. https://www.terveyskyla.fi/tietoa-terveyskylästä/mikä-on-terveyskylä

Honkanen, M., Jousimaa, J., Komulainen, J., Kunnamo, I. & Sipilä, R. 2021. Lausuntokierros. In Honkanen, M., Jousimaa, J., Komulainen, J., Kunnamo, I & Sipilä, R. (Eds.), Hoitosuositustyöryhmien käsikirja. Suomalainen Lääkäriseura Duodecim. Retrieved 3rd July 2021. https://www.terveysportti.fi/dtk/khk/koti

HUS Tietohallinto. 2021. Digitaalisten palveluiden elinkaarimalli. Internal documentation, not published.

Hyppönen, H. & Ilmarinen, K. 2016. Sosiaali- ja terveydenhuollon digitalisaatio. Tutkimuksesta tiiviisti 22/2016. Helsinki: Terveyden ja hyvinvoinnin laitos.

Häyrinen, K. 2018. Social and health care meets digitalization – challenges and possibilities. Finnish Journal of eHealth and eWelfare 10, 186-188.

Interaction Design Foundation. Gamification. Retrieved 6th December 2021. https://www.interaction-design.org/literature/topics/gamification

ISO 9241-210. 2010. Ergonomics of Human-System Interaction - Part 210: Human-Centered Design for Interactive Systems. International Organization for Standardization

Kaartinen, I., Berg, L. & Lagus, H. 2017. Haavanhoitoon kannattaa panostaa. Suomen Lääkärilehti 8, 481.

Krooninen alaraajahaava. Käypä hoito -suositus. Suomalaisen Lääkäriseuran Duodecimin ja Suomen Ihotautilääkäriyhdistyksen asettama työryhmä. Helsinki: Suomalainen Lääkäriseura Duodecim, 2014 (referred 2.3.2020). Available online: www.käypähoito.fi

Las Heras, K., Igartua, M., Santos-Vizcaino, E. & Hernandez, R.M. 2020. Chronic wounds: Current status, available strategies and emerging therapeutic solutions. Journal of Controlled Release 328, 532-550.

Lindholm, C. & Searle, R. 2016. Wound management for the 21st century: combining effectiveness and efficiency. International Wound Journal 13 (suppl. S2), 5–15.

Matveinen, P. 2020. Terveydenhuollon menot ja rahoitus 2018. Terveyden ja hyvinvoinnin laitos. Tilastoraportti 23.

Medical Device Coordination Group. 2020. MDCG 2020-1 Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software.

Melnyk, B. M., Gallagher-Ford, L., Long, L. E. & Fineout-Overholt, E. 2014. Practice Competencies for Practicing Registered Nurses and Advanced Practice Nurses in Real-World Clinical Settings: Proficiencies to Improve Healthcare Quality, Reliability, Patient Outcomes, and Costs. Worldviews on Evidence-Based Nursing 11, 5-15.

Meskó, B., Drobni, Z., Bényei, É., Gergely, B. & Győrffy, Z. 2017. Digital health is a cultural transformation of traditional healthcare. mHealth 38, 1-8.

Moisil, I. 2019. The two faces of healthcare digitalization. Lessons to be learned. Applied Medical Informatics 41, Suppl. 1, 1.

Myers, J.W., Gilmore, B.A., Powers, K.A., Kim, P.J. & Attinger, C.E. 2016. The utility of the surgical safety checklist for wound patients. International Wound Journal 13, 848-853.

Navad, J., Kaihlanen, A-M., Kujala, S., Laukka, E., Hilama, P., Koivisto, J., Keskimäki, I. & Heponiemi, T. 2021. How to Implement Digital Services in a Way That They Integrate Into Routine Work: Qualitative Interview Study Among Health and Social Care Professionals. Journal of Medical Internet Research 12.

Nielsen, J. 2012. Usability 101: Introduction to Usability. Retrieved 3rd May 2021. https://www.nngroup.com/articles/usability-101-introduction-to-usability/

Olsson, M., Järbrink, K., Divakar, U., Bajpai, R., Upton, Z., Schmidtchen, A. & Car, J. 2019. The humanistic and economic burden of chronic wounds: A systematic review. Wound Repair and Regeneration 27, 114-125.

Page, G. & Bordage, G. 1995. The Medical Council of Canada's Key Features Project: A More Valid Written Examination of Clinical Decision-making Skills. Academic Medicine 2, 104-110.

Page, G., Bordage, G. & Allen, T. 1995. Developing Key-feature Problems and Examinations to Assess Clinical Decision-making Skills. Academic Medicine 3, 194-201.

Phillips, C.J., Humphreys, I., Fletcher, J., Harding, K., Chamberlain, G. & Macey, S. 2016. Estimating the costs associated with the management of patients with chronic wounds using linked routine data. International Wound Journal 13, 1193-1197.

Quesenbery, W. 2004. Balancing the 5Es: Usability. Cutter IT Journal 17:2, 4-11.

Regulation (EU) on medical devices. 2017. 2017/745.

Saranto, K., Kinnunen, U.M., Jylhä, V. & Kivekäs, E. 2020. Digitalisaatio ja sähköiset palvelut uudistuvassa sosiaali- ja terveydenhuollossa. In Hujala, A. & Taskinen, H. (Eds.), Uudistuva sosiaali- ja terveysala (179–212). Tampere: Tampere University Press.

Sarcevic, A., Rosen, B.J., Kulp, L.J., Marsic, I. & Burd, R.S. 2016. Design Challenges in Converting a Paper Checklist to Digital Format for Dynamic Medical Settings. International Conference on Pervasive Computing Technologies for Healthcare May 2016, 33-40.

Seppänen, S. & Hjerppe, A. 2007. Haavanhoitotuotteiden saatavuus Suomessa. Selvitys vuosina 2006–2007. Suomen Haavanhoitoyhdistys ry.

Shaw, R., Ramachandra, V., Lucas, N. & Robinson, N. 2011. Management Essentials for Doctors. Cambridge: Cambridge University Press.

Snyder, R.J., Jensen, J., Applewhite, A.J., Couch, K., Joseph, W.S., Lantis, J.C. & Serena, T.E. 2019. A Standardized Approach to Evaluating Lower Extremity Chronic Wounds Using a Checklist. Wounds 31 (5 Suppl), S29-S44.

Tuomi, J. & Sarajärvi, A. 2018. Laadullinen tutkimus ja sisällönanalyysi. Helsinki: Kustannusosakeyhtiö Tammi.

Tutkimuseettinen neuvottelukunta. 2013. Hyvä tieteellinen käytäntö ja sen loukkausepäilyjen käsitteleminen Suomessa. Available at: https://www.tenk.fi/sites/tenk.fi/files/HTK_ohje_2012.pdf.

van Velsen, L., Beaujean, D. JMA. & van Gemert-Pijnen, J. EWC. 2013 Why mobile health app overload drives us crazy, and how to restore the sanity. BMC Medical Informatics and Decision Making 13:23, 1-5.

Vuori, J. a. Tapaustutkimus. In Vuori, J. (Eds.) Laadullisen tutkimuksen verkkokäsikirja. Tampere: Yhteiskuntatieteellinen tietoarkisto. Retrieved 19th May 2021. https://www.fsd.tuni.fi/fi/palvelut/menetelmaopetus/kvali/tutkimusasetelma/tapaustutkimus/

Vuori, J. b. Laadullinen sisällönanalyysi. In Vuori, J. (Eds.) Laadullisen tutkimuksen verkkokäsikirja. Tampere: Yhteiskuntatieteellinen tietoarkisto. Retrieved 3rd July 2021. https://www.fsd.tuni.fi/fi/palvelut/menetelmaopetus/kvali/tutkimusasetelma/tapaustutkimus/

Wilkinson, B. & van Boxtel, R. 2020. The Medical Device Regulation of the European Union Intensifies Focus on Clinical Benefits of Devices. Therapeutic Innovation & Regulatory Science 54, 613-617.

Wilson, C. 2014. Interview Techniques for UX Practitioners A User-Centered Design Method. Waltham: Elsevier Science & Technology.

Wounds International. 2012. International consensus. Optimising wellbeing in people with a wound. An expert working group review. London: Wounds International. Available online: http://www.woundsinternational.com

APPENDIX 1

SUOSTUMUS TUTKIMUKSEEN JA HENKILÖTIETOJEN KÄSITTELYYN

Tutkimuksen nimi:
Validation and Clinical Evaluation of a Digital Wound Management Checklist

☐ Suostun henkilötietojeni käsittelyyn Tutkittavan tiedotteen liitteen 1 rekisteriselosteen mukaisesti.

☐ Suostun vapaaehtoisesti osallistumaan tutkimukseen, jossa tutkitaan digitaalisen haavanhoidon tarkistuslistan käyttöä kliinisessä ympäristössä haastattelu-, havainnointi- ja kyselytutkimuksena. Olen saanut riittävät tiedot oikeuksistani, sekä tutkimuksen tarkoituksesta ja toteutuksesta. Minulla on oikeus milloin tahansa tutkimuksen aikana ja syytä ilmoittamatta keskeyttää tutkimukseen osallistumiseni tai peruuttaa suostumukseni.

Aika ja paikka

Tutkimukseen osallistuvan allekirjoitus ja nimenselvennys

APPENDIX 2

END-USER TESTING QUESTIONS

1. **Key Feature Problem (KFP) Questions**

   For each fictional patient case, there will be same questions. There will be total of seven fictional patient cases.

- Is there any history information you would like to clarify from the patient or from patient records?
- What additional examinations would you make or prescribe?
- What is your leading diagnosis at the moment?
- What would be the next steps you would take for the wound management of this patient?

2. **Usability Interview Topics**

   A. Background information

- Education background and current occupation
- Have you been working with wound patients?

   B. Digital tools and checklists

- Have you been using checklists (paper or digital form) in your work? If yes, in what cases?
- Do you consider checklists useful in your daily work?
- What kind of digital tools are familiar to you?
- Have you been using digital tools in your work?
- How do you feel using digital checklists in your work?

   C. Usability

- What do you think of the usability of Haavapuntari?
  - Was it easy to navigate?
  - Were the instructions clear?
- Did you encounter any issues or problems in using Haavapuntari? Please specify if there were any issues.
- Did you find any particularly good features in Haavapuntari?
- Did you find any particularly bad features in Haavapuntari?

- How did you feel about the suggestions Haavapuntari offered?
- Would you use Haavapuntari in your daily work in clinical setting? Please specify.

APPENDIX 3

CLINICAL EVALUATION QUESTIONNAIRE FOR EXPERT STATEMENTS

- Did you encounter any issues or problems in using Haavapuntari? Please specify if there were any issues.
- Did you find any particularly good features in Haavapuntari? Please specify.
- Did you find any particularly bad features in Haavapuntari? Please specify.
- Were Haavapuntari flow charts clinically accurate?
- Were the suggestions Haavapuntari offered clinically correct?
- What do you think of the usefulness of Haavapuntari during daily work in clinical setting?
- Any other comments?