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Human Factors Engineering and Usability as Key Drivers for Design of Device Suited for Urine Filtration and Enrichment

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Abstract

Evidence-based practices (EBPs) are not always straightforward to implement in a design process, as impacts can be difficult to assess in practice and appropriate methods are not yet established. User-centered design (UCD) offers opportunities to improve implementation of EBPs. UCD refers to the use of rigorous and validated engineering tools to design technology interfaces focused on user goals, such as device safety, effectiveness, efficiency, and user satisfaction. UCD has the potential to improve six core elements of patient-centered care: (i) education and shared knowledge, (ii) free flow of information, (iii) patient engagement, (iv) teamwork, (v) attention to non-medical aspects of care, and (vi) respect for patient preferences. Technological advances in medicine over the past few decades have provided patients with a variety of inventions, such as electronic health record patient portals, home-based medical devices, and smartphone apps. Effective application of UCD principles results in patient-centered inventions that are more likely to ease patients' treatment burden, improve their care experience, increase patient engagement, and enable patients to become more self-sufficient. Here, the URICH device design process is used as case-example to demonstrate the inclusion of usability testing and all users as early as possible in the product design and development process.

Keywords: urine; liquid biopsy; usability; human factors engineering; user-centered design; psychology; geographic locations; aesthetics; brainstorming; Biobank personnel; demographics; self-efficacy

Introduction

The term medical device is used for a wide range of products used in a variety of settings for the diagnosis, prevention, monitoring or treatment of illness or disability. According to the European Medicines Agency (EMA), "medical devices are products or equipment intended for a medical purpose"[1]. In the European Union (EU) medical devices must undergo a conformity assessment to prove they meet regulatory requirements to ensure they are safe and perform as intended. Manufacturers can place a CE-mark on a medical device once it has passed the conformity assessment [1]. For this conformity assessment the European Union published in 2017 the Regulation (EU) 2017/746 (IVDR). This Regulation applies to all in vitro diagnostic medical devices that would be placed on the market or put into service in Europe. This regulation sets high standards of quality and safety for in vitro diagnostic medical devices by ensuring, that data generated in performance studies are reliable, robust and that the safety of subjects participating in performance studies is protected [2]. In addition to conformity, the International Organization for Standardization (ISO) has developed many international standards with all different focusses, such as medical device development, quality management, risk management, usability, etc. [3]. These standards are developed in any domain to assure consumers that their products are safe, reliable and of good quality [3].

In this paper, we aimed to first provide some background on the use of user-centered design and usability testing in product

design and development processes. Secondly, we use the design process of the URICH device as case-example to demonstrate the inclusion of usability testing and all (end-)users as early as possible in the product design and development process.

Background

User-centered design

Evidence-based practices (EBPs) are not always straightforward to implement in a design process since impact in practice can be hard to assess and proper methods are not yet established. Examples of these design problems currently not supported by EPB are low ease of use, high complexity, and poor fit with the intended delivery context [4]. Looking beyond traditional implementation strategies, user-centered design (UCD) offers potential for improving the implementation of EBPs. Starting from research in human-computer interaction, user experience design, service design, and cognitive psychology, UCD experts apply concepts and strategies related to the design, evaluation, and implementation of innovations for human use and to the study of main characteristics of optimal user-interaction [4,5]. UCD refers to the use of rigorous and validated engineering tools to design technology interfaces focused on user goals, such as safety, effectiveness, efficiency, and user satisfaction of devices [6].

UCD has the potential to improve the six core elements of patient-centered care: (i) education and shared knowledge, (ii) free flow of information, (iii) patient engagement, (iv) teamwork, (v) attention to non-medical aspects of care, and (vi) respect for patient preferences [6]. Technological advances in medicine over the past few decades have provided patients with a variety of inventions, such as patient portals for electronic health records, home-based medical devices, and smartphone apps [6]. Effective application of UCD principles results in patient-centered inventions that are more likely to ease patients' treatment burden, improve their care experience, increase patient engagement, and enable patients to become more self-sufficient [6]. However, if the UCD principles are not applied correctly and users' needs and expectations about how the device functions are not taken into account, this can have harmful consequences [6].

UCD plan of approach

A first step in a UCD action plan is to make a complete overview and specification of all stakeholders and prioritize them, as the design and development team must first gain explicit view of stakeholders and then balance the needs and limitations of these stakeholders [7,8]. Stakeholders should be identified exhaustively and in a broad context, including any user who can reasonably be expected to use the device during its lifecycle, such as users, physicians, nurses, technicians, maintenance personnel, healthcare providers, regulatory organizations, and the designing institution [6,8,9]. It is important to consult a wide range of specialists with different levels of experiences to address the clinical needs, human error, and patient safety [6,9]. This is necessary because potential users range from largely untrained lay people to highly skilled professionals, and in the case of home-based devices, users may have physical or cognitive limitations or living in difficult geographic locations [10]. Another important remark to make is that users and payers (person making a purchasing decision) are often different individuals or entities in the medical context, which allows tangible benefits to end-users to be subordinated to other considerations, such as benefits to customers and other decision makers [11]. After all relevant stakeholders have been identified, their involvement is needed to identify requirements, information about users' capabilities, and methods to assess design decisions from these perspectives [8].

A second step is to compile all information to identify every stakeholder who can reasonably be expected to use the device during its lifecycle. Importantly, to design products that satisfy their target users, an understanding of relevant user characteristics is necessary. These user characteristics include cognitive aspect (e.g., technical skill, spatial reasoning, adaptability, sensitivity to stereotype, memory, and prerequisite content knowledge), personality (e.g., patience, locus of control, optimism, perfectionism, changeability, uncertainty, avoidance, self-efficacy, and exposure to marketing), demographics (e.g., age, gender, culture, income, and grown-up place), physical characteristics (e.g. strength, body dimensions, reach envelope) and use behavior (e.g., frequency of use, avoidance of using complex products, buy decision, complaining attitude, and familiarity with devices) [7].

Usability

Usability is a broad term that has many perspectives on its definition. However, the most widely accepted definition is formulated in the ISO 9241-11 standard and is "The extent to which a system, product or service can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use" [12]. It is expected that a high level of usability leads to increased productivity and adoption of the technology for the user, increased safety, and reduced effort for operation. Furthermore, positive experiences with a product result in a stronger brand position and (re)purchase intent, while negative experiences can result in product returns, complaints or helpdesk calls [7].

To ensure that a device is the right device with the right components, meeting the un-met or poorly met needs, usability validation requires end-user involvement during the concept and pre-concept stages of device development. This is also prescribed by the regulations and found in literature [13]. However, not many manufacturers incorporate usability as early as possible, which may be because the user perspective emphasizes on the human factors engineering process at the design phase, which could interfere with the quality and risk identification factor of new products [14].

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Usability is also referred to as Human Factors Engineering (HFE), Human Engineering (HE), Usability Engineering (UE), Human Computer Interaction (HCI) and Ergonomics. Much attention goes to usability requirements, heuristic evaluation and ergonomics in guidelines and standards for medical device development, therefore manufacturers have the responsibility to ensure patient safety by emphasizing on the HFE process in the design of devices [15]. HFE studies help to increase safety, reduce potential errors, decrease training, increase ease of use, improve task performance, optimize device use, enhance user satisfaction, lessen product liability risks, facilitate the regulatory approval process, and increase the chance of commercial success.

Regulatory base for usability testing in device development

The BS EN 62366-1:2015+A1:2020 (Medical devices – Part 1: Application of usability engineering to medical devices) is the main European harmonized standard that defines a process for a manufacturer to analyze, specify, develop, and evaluate the usability of a medical device as it relates to its safety. This last standard references the risk management BE EN ISO 14971:2019+A11:2021 (Medical devices – Application of risk management to medical devices) as the base for the identification of usability matters via a risk management process.

Methods for usability validation

Various methods can be used for usability testing such as heuristics, cognitive walkthroughs, focus groups, observation, explorative vs. comparative tests, etc. The design and development team must decide which methods to use or to combine in depending on several factors, such as the stage of the design of the device, the type of users involved, the expertise of the research, the type of information required, and the materials, time and money available [8,16]. The required level of usability validation will depend on the criticality of the device, its environment of use, the primary operator, as well as the party paying for the device [16].

General product design process

Generally, the product design process (Figure 1) involves several steps or phases, starting from defining the problem and ending with commercialization. Each phase is crucial in ensuring that the product meets the requirements of its users, is functional, aesthetically pleasing, and can be produced at scale. The first phase is called the define phase. In this phase, the problem that the product will solve is defined, along with the requirements for the product, its target users, and the context in which it will be used. The possible market for the product is also investigated and described. The ideation phase comes next, and it involves further research, brainstorming, and analysis of the user and context of intended use. The goal of this phase is to generate new ideas for the product that ought to meet the requirements set in the first phase to solve the problem defined. The market phase is linked to the first two phases. Here, the competitive advantages, area of innovation, product identity, and costs are investigated and preliminarily determined.

Once these initial phases are complete, the development phase begins. During this phase, the product idea is transformed into sketches, prototypes, product visualizations, and 3D models. Design factors such as configuration, function, ergonomics, aesthetics, materials, and production are also investigated and determined. After the initial prototypes and 3D models are created, the testing phase begins. This phase involves experimenting with different versions of the product, eliminating options, and making improvements until a satisfactory final prototype or 3D model is created. This final prototype is then refined until it is ready for production.

In the production phase, partners needed for production are secured. The assembly and packaging of the product are also defined. The decisions made during the design factor phase, such as the product category and material types, become important in this phase. The production phase ends with the creation of the final product, validation testing, and quality assurance protocols. Finally, the product is ready for the world, and commercialization can begin. The product development team transfers the product to marketing for a product launch and further commercialization.

The URICH device, as case-example

The design and development process of the URICH device will be thoroughly discussed, however without mentioning intellectual property sensitive information, since possibilities for patenting are under investigation. The aim of the design and development of the URICH device is to perform an upfront enrichment of urinary analytes at the side of the user. An important opportunity in healthcare is to optimize the process of self-sampling at home or in the clinic. It is becoming more and more clear that patient self-sampling or remote sample collection from clinical facilities offers benefits, as there is an increase in efficiency and speed of clinical trials, the allowance for additional sampling time-points, a reduction in patient burden, the opportunity for broader and more diverse participation in clinical trials and, a higher participation in screening [17]. Despite these benefits, the uptake of self-sampling in clinical trials and screening programs has been slow, mainly due to questions about the quality of self-sampling, sample stability and comparability with the gold standard methods. However, these challenges could potentially be overcome through patient training and using sample-collection devices that make sample collection easier and more convenient, which in turn could improve the data collection accuracy [18]. Urine has great potential as a non-invasive liquid biopsy for self-sampling and screening, thereby possibly optimizing healthcare. The Colli-Pee® device (Novosanis, Belgium), having different configurations to allow for volumetric and standardized collection and immediate preservation of first-void urine, which helps increasing self-sampling uptake. Preservatives such as UCM® or UAS™ guarantee

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the sample integrity during postal transport for up to 7 days. This makes it possible to send samples from the general practice or patient's home to the lab by postal mail or parcel services. URICH allows expanding the Colli-Pee® device portfolio to collect a urine sample that improves meeting the requirements of current oncological research and cancer care by enabling concentrating or filtering of the urine sample.

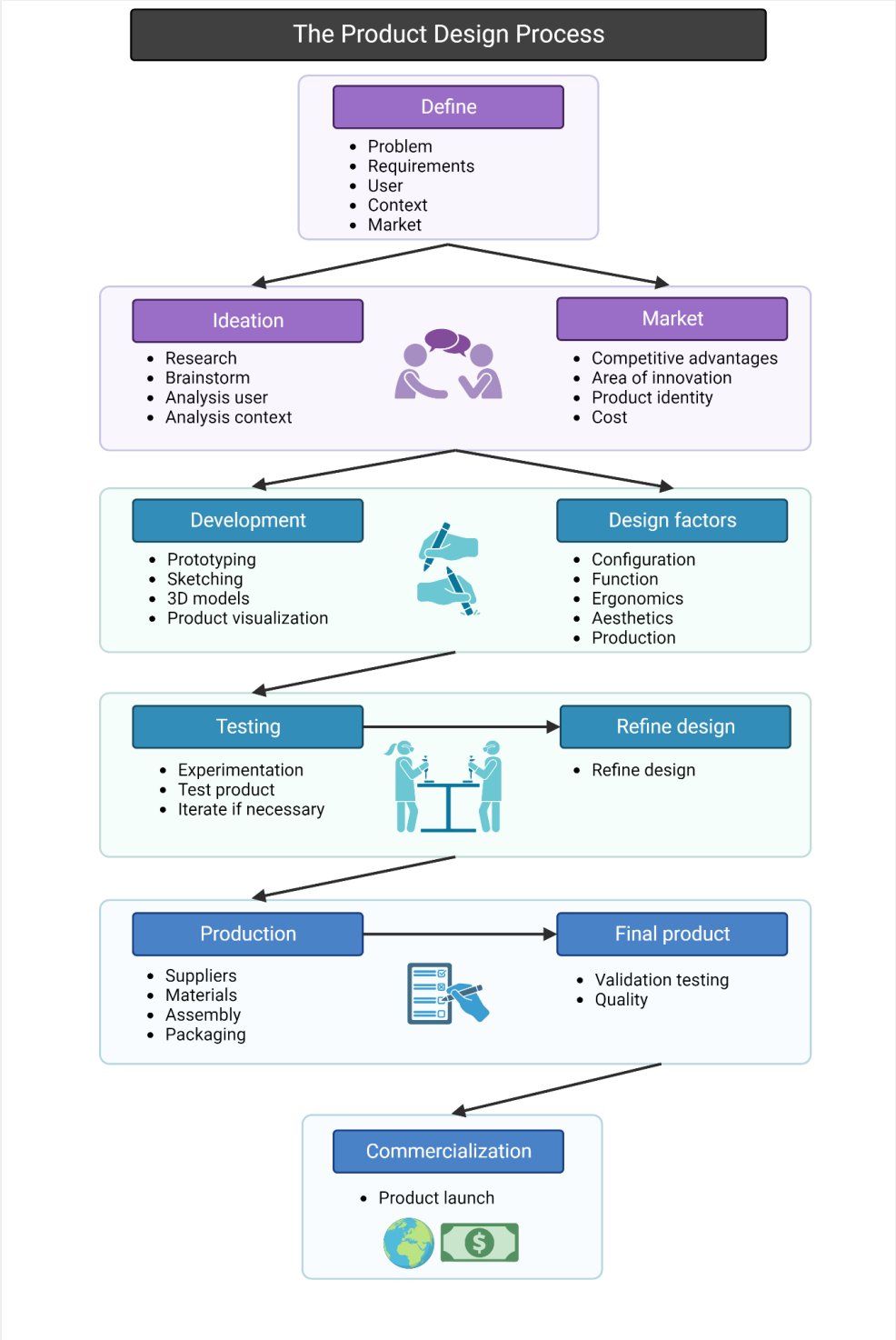

Figure 1: The Product Design Process.

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Define phase

Problem statement

The three key steps in a liquid biopsy workflow include: (i) biofluid collection (including collection, storage, and handling), (ii) concentration, isolation, or extraction of biomarkers and (iii) analysis or detection of biomarkers. Each of these steps brings possible variation and thus offers opportunities for optimization and standardization [19]. For example, cancer researchers are investigating different cancer types, different analytes of interest and different sample types, all with the goals of early detection of cancer, screening for cancer, follow-up of disease progression, monitoring of treatment response and prediction of recurrence [19]. Biologically, different analytes require different preservation, storage, and handling conditions. Ideally, every analyte of potential interest in the sample is immediately properly preserved to withstand analyte degradation under transportation conditions. Furthermore, in urine samples these analytes of interest can be highly diluted. Therefore, lab technicians perform concentration or filtration steps on the sample before the sample can be used in isolation and extraction procedures to isolate the analyte of interest and prepare it for downstream analysis.

Identification stakeholders and user groups

Based on this application of cancer research, for the design process of URICH different stakeholders and user groups have been identified by brainstorming on all possible individuals who can reasonably be expected to use the device during its lifecycle:

a) Actors in design of medical devices (University of Antwerp, Novosanis, OraSure Technologies and DNA Genotek Inc.)

b) Physicians and other healthcare professionals (e.g., prescribe/recommend device, hand out/send device for screening, etc.)

c) Users (patient, screening participant, person interested in own health, etc.)

d) Postal service (sending samples to laboratory, etc.)

e) Lab technicians (receive samples, further processing for analysis, etc.)

f) Biobank personnel (receive sample, further processing for storage, etc.)

g) Person making a purchasing decision (e.g., government for population screening, etc.)

h) Regulatory organization (e.g., FAGG, FDA, etc.)

Ideation phase & Market research

Identification users and their characteristics

The URICH project will focus on sample preparation by the user and processing by the lab technician or Biobank personnel. URICH will relocate a few steps from the lab to the user to better preserve the sample during transport and storage. After collection and execution of possible additional steps, the user sends the sample to the laboratory or the Biobank. The lab technician receives the URICH-sample and performs the needed steps before using the sample for isolation or storing it for further use. On the other hand, when the Biobank personnel receive the URICH-sample they store it for clinical research.

When looking at the URICH users, being the potential patient or person interested in its health, there are three main groups that can be identified: people who would use URICH (i) for disease diagnosis, (ii) in a disease screening trajectory and, (iii) for health monitoring. These three groups will have different frameworks around their sample collection process. When a person receives URICH for disease diagnosis, there will be a large framework since the healthcare professionals will provide the device and the necessary explanation to the potential patient. For the monitoring process, there can be healthcare support when the sampling occurs in the clinic. However, monitoring usually means repeated use of the device, which allows to expect experienced users. The screening trajectory is the process in which there is almost no framework and users must rely on the instructions for use. On top of the different frameworks around the sample collection process itself, users can vary significantly when it comes to characteristics. Sadly, cancer is a disease of all people, it doesn't differentiate between cognitive aspects, personality, or demographics. People of all ages, gender, culture, income, technical skills, adaptability, use behavior, etc. can be diagnosed with cancer and are therefore potential users of URICH. It was decided that the most critical group would be the 80+ age group, because of potential age-related ailments and strength decrease that could affect autonomous use. The aim of URICH for these 'first' users is to make the sampling process and all necessary steps as easy as possible for all potential users, while enabling self-collection in the comfort and privacy of the user's home and shipment of the URICH-sample to the laboratory.

The second and third group of URICH-users are the lab technicians and Biobank personnel, which have many similarities. One of the most important characteristics is the fact that lab technicians and Biobank personnel are trained users with developed technical skills. Furthermore, these second and third groups of users can be people between 18 and retirement age, all genders, all culture, and all use behaviors. The aim of URICH for these users is to make the laboratory processing and all necessary steps as easy, as fast and as convenient as possible.

Market research in collection, preservation, and enrichment

The scope of this project is supporting the process of collecting a urine sample, filtrate/concentrate and preserve the desired fraction and analytes, preparations in the receiving laboratory. Currently this entire workflow is not integrated into

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a streamlined process and is therefore performed using a chain of different products that each support 1-2 steps. Other solutions for urine collection devices and preservatives are available. The devices are developed for the collection of urine, some enable the collection of a specific fraction and/or specific volume and/or direct preservation. While literature searches have shown that both laboratory available chemicals as well as commercially available preservatives are used for oncological research [19]. Preservatives can be developed for a specific sample type or specific analyte or as a general preservation method, however all commercially available methods have their own claims. Usually, the filtration or concentration of the urine sample is performed in the laboratory environment. Where a lab technician pipettes the urine sample into specific developed devices such as, Amicon® centrifugal filter devices and Vivaspin® centrifugal concentrators (Figure 2). Both solutions use centrifugation to provide the force to rapidly remove solvents and small molecules through the ultrafiltration membrane. On the other hand, Per Guldberg developed a 'filtration device' for on-site collection, storage, and shipment of cells from urine[20], which is the first mention of the user performing the filtration step. Up to now the filtration device of Per Guldberg has been described in research solely and has not yet been commercialized (Figure 2). As seen in the competitive field, the process support during collection for the user and during processing for the lab technician is not yet offered, and therefore is one of URICH's biggest unique selling propositions.

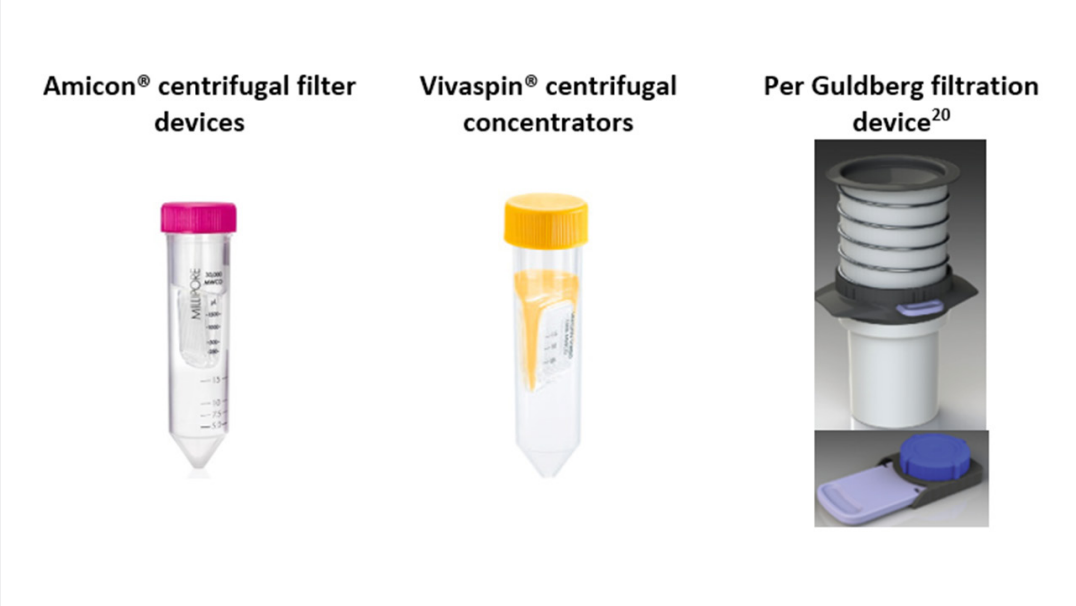

Figure 2: Overview of filtration and/or concentration devices.

Brainstorm

Several brainstorming sessions were executed. In the first brainstorm, the full trajectory of a urine sample was mapped using scenario envisioning. Thereafter, creative sessions were performed to sketch and map out as many different ideas as possible, which resulted in a number (usually for further design processing max 5 ideas are recommended) of innovative start ideas. These innovative initial concepts were weighed against each other in a trade-off-matrix based on predetermined criteria. For URICH, these criteria were chosen with a strong emphasis on the users and their experience: readability, the number of steps, simplicity per step, lab compatibility, and feasibility. After the determination of the criteria, the innovative start ideas are scored out of 5 on each criterium, where 5 is the highest and 0 is the lowest score. The combination of these revealed the final score of that innovative start idea.

Development

The transformation of the product idea into sketches, prototypes, product visualizations, and 3D models did not involve user perspectives or engagement and will therefore not be discussed in this paper. However, the first sketches and graphical visualizations were included in Figure 3 to provide some context about the URICH device.

Design factors

Design factors such as configuration, function, ergonomics, aesthetics, and production for URICH were investigated and determined. First, several targets of interest (TOI), also referred to as requirements, related to the users can be defined for URICH. All these different TOIs lead to their own specifications and functioning that must be considered when configuring the final product. Furthermore, the necessary ergonomics and aesthetics for the users are determined.

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Figure 3: Graphical visualization of the URICH device and its packaging.

Functioning & configuration

The first step is the collection of urine, which is done using Colli-Pee®, leading to TOI 1 "a system that collects first-catch urine in a tube containing the filter module". The first TOI will not be discussed, as this is mainly the configuration of the CE-marked Colli-Pee® devices.After the urine collection, URICH is used to perform the filtration and it should enable filtration for the user at home, translating to TOI 2 "a system that facilitates the power of the user so that the sample is filtered through the filter module". The user specifications are: (i) it must be clear which part of the package is URICH and how to assemble it, (ii) the force required must be limited to 0.8Nm or 60N torque, pushing or pulling force (e.g., user's capabilities), (iii) there should be feedback (e.g., auditive ['click'], tactile, haptic, visual feedback) to the user that the step was successful, (iv) it must be user-friendly for people of all ages and, (v) only successful execution of a step will physically enables the next step.

Next it is important that the residue and filtrate are and remain separated throughout transport to the laboratory, which leads to TOI 3 "a system to store both samples with the correct preservatives". The following user specifications were determined: (i) the user must understand which part belongs where in which orientation, (ii) the force required must be within the user's capabilities, (iii) there should be sufficient feedback to the user that this step has been completed successfully, (iv) the sample must comply with transport requirements.

Upon arrival at the laboratory, URICH supports the lab technician in the further preparation of the sample, resulting in TOI 4a "a system that adds solvent to the residue" and TOI 4b "a system that stores the residue dissolved in the solvent during centrifugation". The user specifications were set as follows: (i) only one configuration of the parts should be possible, (ii) the mounting should be feasible by hand, (iii) the sample must be compatible with standard centrifuges, (iv) the product should withstand centrifugal forces up to 6000g, (v) the product should be balanced to avoid vibration during centrifugation and, (vi) the product can be disassembled by a lab technician after centrifugation. Finally, the lab technician needs to be able to pipette the filtrate from the URICH components into the isolation components, leading to TOI 5 "a system that enables pipetting". Therefore, only one user specification is determined, being that the URICH configuration after centrifugation requires an angled bottom for easy pipetting.

Ergonomics & Aesthetics

URICH should be intuitive, easy, and user-friendly for all user groups. To achieve these ergonomic specifications and the above described TOIs, some ergonomic and aesthetic choices will be made. The number of steps to be performed by the user for collecting and filtrating the urine sample and shipping the preserved sample and the complexity of these steps will be limited, to keep URICH as intuitive and easy as possible. The decisive for ease of use will be the time and power required by the user to perform the filtration step. Additionally, the decipherability of the various parts of the URICH components will be improved by smart color coding of the various parts. By coloring the components that will replace each other in the same color, the process becomes more intuitive and clearer.

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Testing

During the testing phase, different simulations, experiments, and studies can be performed to examine the functioning of product components, critical aspects, functioning of the product, usability, and readability of URICH, instructions for use (IFU), and packaging. All these different tests can be executed with prototypes, 3D prints or with the actual molded product. In this paper, the critical user-related tests are described.

Pressure test

This experiment was designed to investigate the pressure required for the filtration steps in the URICH variants. For this experiment, the final design has been approached as closely as possible by working with syringe filters and collecting first-morning first-catch urine and first-catch urine (corresponding to the most critical scenarios possible). The set-up for this experiment consisted of three formats wherein raw urine is aspirated with the syringe and then filtered using (i) a 5.0-micron syringe filter, (ii) the combination of a 5.0- and 0.8-micron syringe filter or, (iii) the filtrate from the 5.0-micron syringe filter is refiltered with a 0.8-micron membrane. This specific set-up of formats enables to find the resistance of each membrane separately and together. Each test is repeated three times at a different speed. The measurements of these tests allow to assess the flux of each membrane, which is linearly related to the pressure. This estimation of pressure determines the necessary torque from which the diameter of the plunger head to accommodate the user's strength can be derived. Further analysis of the results showed that the components are calculated for a maximum axial force of 100N at 10s. And that the maximum measured and calculated force for URICH at a filtration time of 10s is 88N.

Usability of URICH – related to readability of IFU and packaging

The usability and readability of URICH in combination with the IFU and designed packaging was examined with low-fidelity prototypes of URICH in the packaging, without the actual urine collection and filtration, by asking users what steps they would take and why. Because the 3D prints could not be made transparent and were not printed in the right colors, the test-persons were shown a picture after each step of how the device/sample would look at that point. For this test, at least seven naïve people were included. Each of their responses and actions were recorded until the entire process from collection to shipment to the lab was completed. Based on the observations of this experiment some changes were made to the packaging and IFU to decrease the potential human errors and increase the intuitiveness of URICH.

Future Perspectives

The first steps in the URICH product design process have been taken, but there are still some phases to be completed such as the development phase, researching the design factors, testing and finally refining the final design. After completing the design, the Design and Development control phases can be started, with research into the production information to determine the supply chain and the verification, validation and quality assurance of the final product [21]. When the final product is fully validated, and the quality assurance protocols are in place the commercialization phase can begin in which the product is launched to the market.

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