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Dealing with Ecological Validity and User Needs when Developing Simulation Based Training Equipment – Case Study of a Medical Palpation Task Trainer

Daniel Nygård Ege[a]*, Oscar Lilleløkken[a], Marius Auflem[a], Martin Steinert[a]

[a] *NTNU Trondheim, Richard Birkerlandsvei 2B, Trondheim 7491, Norway*

* Corresponding author. Tel.: +47 465 03 255. *E-mail address:* danieneg@stud.ntnu.no

Abstract

Simulation-based training offers a safe and repeatable environment where users can increase their skill level. Development of products facilitating such training is, however, faced with high uncertainty and ambiguous requirements. This complexity is a result of the intended use-cases, required product functionality and required approximation of clinical realism. In order to explore such uncertain aspects of simulation-based training equipment, two interesting factors are considered; user needs and ecological validity. This paper presents a case project where a medical palpation task trainer has been developed. In this case, a medical diagnostics procedure has been enabled through specific product functionality. As the complexity associated with simulators makes it difficult to elicit and fixate requirements, this paper highlights the benefits of using prototypes during the early stages of development. By presenting prototypes and testing these with both experienced and novice users, developers could better understand complex use cases and product interactions. Through case examples it is shown how prototyping extensively in various domains and levels of abstraction could help elicit product requirements as well as enlighten unknown problems and corresponding opportunities. In order to create products facilitating effective training, training scenarios must be made sufficiently realistic, i.e. ensuring ecological validity. To accomplish this, a simulator concept must encompass realistic tasks and physical attributes. Further, the potential of the conceptual prototype is discussed where self-directed learning and learning algorithms are of interest. Future research will, therefore, be focused on improved medical training and consequently training devices.

Keywords: Prototyping; Prototype-Driven Development; User-Centerd Design; Ecological Validity

1. Introduction

Developing products to enable simulation and simulation-based training can be associated with a lot of ambiguity and uncertainty, given complex user scenarios and attributes. Products encompassing human computer interaction in the context of simulation, offer challenges such as recreating complex scenarios and realism in physical functions and features [1]. Developers may aim to recreate the real world for their users to be better prepared for real world scenarios, enabled by training in a low risk environment, such as in driving- and flight simulators. Hence, medical task trainers and the development of these are also associated with this product context. Such products may encompass vastly different success criterions, but the necessity of eliciting requirements is key for all of them in the early development phase. The complexity associated with simulators, and their interaction, makes it difficult to elicit and fixate requirements. In order to create products facilitating effective training, training scenarios must be made sufficiently realistic. To accomplish this, the simulator has to encompass realistic tasks and physical attributes[2]. In order to map out uncertain aspects regarding

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the development of such products, *user needs* and *ecological validity are* two interesting factors to consider.

User needs can be uncovered and evaluated through conversation and prototype testing with expert users[3,4]. By presenting a case project, this paper exemplifies how a user-centered and prototype-driven development framework is used to elicit requirements. With the goal of designing a medical task trainer to impact how palpation is trained in medicine[5], two known challenges in early stage product development are addressed. Firstly, the user-centered design challenge, of identifying and addressing a user's needs. This could be done by eliciting users pain points and creating a conceptual solution for this problem. Secondly it concerns the complexity and ambiguity facing design teams and exemplifies how prototyping answers design questions through providing tangible insights. These are made tangible through both designing and building prototypes, but also through the interactions between users and conceptual prototypes [6].

Kushniruk et al. (2013) argues that human behavior is dependent on their environment, and therefore ecological validity is required to ensure that tasks/training objectives are applicable to the real world. The parameters encompassed in ecological validity are tasks being performed, users involved, the training scenario and training environment. In the context of this paper, ecological validity is considered a prototype's ability to facilitate training of tasks, by presenting functionality and attributes appropriate for the user to perform them. These attributes can be physical, like the look and feel of a prototype, and intangible, e.g. feedback provided to the user. Ecological validity can be measured by how closely a simulated scenario or task compares to its real counterpart. Ensuring a sufficient degree of realism is necessary to maximize learning outcomes and avoid false learning.

1.1. Prototypes and Prototyping

In this paper, prototypes are considered tools to enable learning [4]. Learning as an activity, where insights are created and made tangible through the creation and interaction with prototypes. Prototypes are, by this, merely the physical outcome from prototyping activities, but for the designer they serve as physical embodiments of concept potentials. Prototyping is considered a critical activity in the early phase of product development, as it is a powerful tool to facilitate learning, communicate and inform decisions [7,8]. In this phase, the goal of designers is to address the uncertain aspects, unknown unknowns, identify product potentials, and eliciting functional requirements for a given concept [9,10].

However, determining critical functions and consecutively the functional requirements is not evident in early stage product development. Aligning with users' needs and adapting to feedback could be challenging as a result of disciplinary and/or organizational boundaries. Prototypes are in this context important tools in crossing these boundaries and facilitate communication [11]. Here, the designers should be reflective in their prototyping activities and bear in mind all the features of any given artifact acting as the prototype [12]. Prototypes should be realized with focused purposes in order to test core assumptions and test out specific aspects of eventual designs [13,14].

1.2. Aim and Scope

The scope of this paper is to exemplify how prototypes can aid development of products encompassing complex attributes and user scenarios. This is done by considering the ecological validity of conceptual prototypes, and eliciting requirements in a user-centered and prototype-driven framework. The paper presents a case project where a medical palpation task trainer has been developed and generalizes the learning outcome of the project. Furthermore, the paper aims to show how product potentials and thereby functional requirements could be identified through user interaction and prototyping. Further it will be shown how users' tacit knowledge, could be made explicit and tangible to designers, when evaluating concepts with expert users.

2. Development of a Conceptual Task Trainer

In the case project presented below the aim has been to explore solutions for an abdominal examination task trainer. Medical task trainers are equipment enabling users to practice technical skills in low risk, repeatable environments [15], and could enable training of novel and/or challenging medical tasks and recognizing conditions and symptoms too rare or dangerous to perform on real patients. As with other projects aiming to recreate real world procedures, ecological validity and user needs are essential parameters to consider when developing a conceptual prototype.

A product potential for such a task trainer was revealed, as students in training practiced on each other, without any additional training aids available. Practicing on a healthy stomach makes it hard to prepare for a real examination, as several symptoms are not possible to simulate. There are also great variations between tests. This became the initial starting point for the project proposed by a medical training device company. Without fixed predeterminations, the development team utilized a user-centered design approach to evaluate a product potential as well as generate a conceptual prototype.

2.1. Exploration of the Use Case

When working with complex problems, such as when designing simulator-based training equipment, defining and evaluating functionalities can be challenging. By providing feedback on prototypes, expert users can aid developers in mapping out needed functionalities, as well as identifying requirements for such functionalities. In the context of this project, expert users are trained medical personnel. Even if trained professionals are not the primary users, their tacit knowledge and experience is vital, and their interaction with prototypes are a key part of iterative prototyping. Contact with expert users is especially valuable in the medical field, given a large chasm between professions, knowledge bases and expertise in the field [16].

Early consultation with expert users gave insight into how an abdominal examination is conducted. Diagnosis of the abdomen requires different symptoms to be identified that may be divided into three main categories: the tactile feeling of the stomach, location of pain, and bowel sounds. When exploring ways to replicate the users sensory experience and interaction with the product, prototypes replicating its physical attributes were used.

The diseases commonly identified by palpation, and which would be most relevant for the abdominal task trainer to simulate were described by expert users. Most diseases are identified by the location of abdominal pain, and the detection of enlarged organs. As shown in Table 1, six diseases and corresponding symptoms [5] were selected for simulation.

Table 1. Most common abdominal diseases with typical symptoms

Disease	Typical symptoms
Appendicitis	Pain in lower right quadrant of stomach
Diverticulitis	Pain in lower left quadrant of stomach
Peritonitis	Pain all over stomach, rebound tenderness
Inflamed gallbladder	Pain in upper right quadrant, gallbladder detectable by touch under ribcage
Inflamed liver	Liver detectable by touch below ribcage
Pancreatitis	Upper abdominal pain

Required functionalities was mapped out based on the diseases chosen for simulation, as shown in Table 2. The medical symptoms were translated into technical functionalities in a product-oriented context; a realistic tactile experience and visual attributes of the abdomen, being able to localize pain, and having the ability to simulate inflamed organs. In the following sections, these functionalities are explored by prototyping and described in further detail.

Table 2. Sub- functionalities prioritized for each function by expert users

Functionality	Sub-functionality
Accurate tactile experience	Firmness of stomach
Pain response	Visible indication of pain
	Indication of pain intensity
Physical resemblance	Has the shape of a stomach
	Includes hipbones and ribcage
	Other parts of appearance must not compromise immersion
Inflamed organ simulation	Possibility to simulate inflamed organs
	Turn on/off inflamed organs, according to different training scenarios
	Realistic tactile experience
Selection of illness	Illness selectable by user

2.2. Prototyping Physical Attributes

Quantifying attributes such as tactile feeling and visual resemblance is challenging and requires expert users opinions to be recreated in a task trainer. Prototypes with different attributes were created so users could test and provide feedback.

2.2.1. Tactile Experience

Aiming to rapidly develop a testable prototype which feels like a stomach, a large plastic container was filled with foam and water filled condoms, as depicted in Fig. 1. A PVC sheet was stretched over to resemble skin, and resulted in a soft, deformable stomach, replicating interaction with the future task trainer. An expert user tested the prototype and raised a concern regarding the uneven feel of it.

Fig. 1. Expert user testing a simple prototype.

Several other materials were proposed to resemble the stomach, some shown in Fig 2., and was internally tested. When a viable possibility was uncovered, a new prototype was tested with an expert user to verify it as a viable solution.

a b

Fig. 2. (a) Ballistic gel with different mix ratios was used to mimic the feeling of a stomach; (b) A multi-layered silicone model offered robustness as well as being soft to the touch.

A shortcoming in using fellow students as markers when training abdominal examinations, is the inability to simulate change in tactility of the abdomen. This might happen as a result of inflamed organs, that could indicate a serious disease. Some organs swell and become detectable by touch when inflamed. An interview with an expert user revealed that the feel of some inflamed organs was only provided through literature. Simulating this in a task trainer enables practice in identifying such symptoms, which is not possible when practicing palpation on a healthy stomach.

An example of an organ detectable by touch when inflamed is the gallbladder, described to feel like a soft lump about the size of a plum when inflamed. With a description as vague as this, the need for prototyping and iterating was apparent to simulate it. Internal tests were done to match the description and validated by expert users.

Fig. 3. Simulating an inflamed gallbladder was done by inflating a balloon with water.

2.2.2. Visual Resemblance

In the field of simulation-based training equipment, it is believed that increasing fidelity and visual resemblance does not necessarily increase learning outcome [17]. It can be argued that expert users with a lot of experience do not require a high-fidelity task trainer to practice. However, when teaching students, being novice users, an unnatural looking simulator could ruin immersion and lead to less learning outcome.

Steps were taken to make an immersive simulation. The prototype depicted in Fig. 1 was implemented in a CPR training mannequin in order to enhance realism. Adding a ribcage and head to the container resulted in a more realistic task trainer, as shown in Fig. 4.

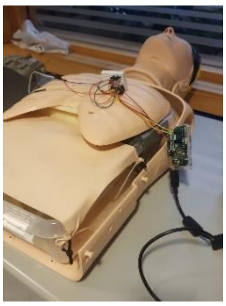

Fig. 4. Integrating a prototype in a CPR mannequin increased realism and immersion.

The iterative process of making a more visually realistic prototypes was done in order to increase immersion of the task trainer. This allowed for not only testing of physical attributes, but facilitates a more realistic, ecologically valid training scenario.

The final prototype was integrated in a medical simulation mannequin, as shown in Fig. 5. Besides demonstrating future integration opportunities in a mannequin, an increased natural look was achieved by having realistic proportions to a human torso, as well as encompassing anatomical landmarks.

Fig. 5. Prototype integrated in medical simulation mannequin.

2.3. Prototyping Functionality

Prototypes are useful in eliciting expert user's tacit knowledge, as described earlier. This knowledge is important when designing prototypes that look and feel realistic and provide an opening for discussion. However, prototype feedback does not ascertain in what degree a prototype is ecologically valid. To establish this, designers must consider how a task can be broken down into tangible objectives, that could be recreated and enabled by a physical model. Hence, necessary input and output parameters must be considered. For instance, when designing a flight simulator, input parameters such as flight controls and switches must be present, while output such as visuals must be recreated in a sufficient way, in order to be ecologically valid.

By breaking down a medical procedure into input and output parameters, distinct prototype functionalities can be established. In the context of this paper, where the procedure at hand is abdominal examination, inputs and outputs are determined by disease symptoms. The procedure is broken down, or translated, into functionality and corresponding requirements for the task trainer. The main input parameters were found to be pain localization and intensity. Pain feedback was determined to be the main output parameter.

2.3.1. Pain Feedback

According to expert users, locating pain and understanding the severity is a necessity when diagnosing an abdominal illness. Detecting touch in a soft material was considered an unknown, and prototyping was fundamental for discovering solutions. A way to display pain resembling what happens in real life was selected through dialogue with users.

Implementing a simple sensor system controlled by a microcontroller, allowed the expert user to detect the location of a force sensor under a PVC skin by palpation, as depicted in Fig. 6. Pain intensity was represented by numbers between 1 and 10 and printed on a separate screen next to the prototype in real-time. A limited number of diseases are possible to simulate by using one sensor, but the concept of using force sensors for both locating pain and detecting pain intensity in a soft material was verified.

Fig. 6. A force sensor offered pain and location feedback in the soft stomach.

Adding sensors to the stomach increased the number of simulatable diseases by delivering sufficient position and force measurements. Having the possibility of differentiating between palpation in each of the abdominal quadrants, the expert user was able to diagnose the task trainer for diseases such as diverticulitis and appendicitis. An LCD screen was implemented to display pain intensity, and printed messages such as “I’m feeling fine” and “this hurts”, to simulate a patient’s reaction to pain while being examined.

The expert user requested an easier visible display distinguishing between levels of pain. By mimicking the numeric pain scale often used in hospitals, a colored LED strip was introduced, replacing the screen. This increase in realism put the simulation closer to what users experience in real life, thus facilitating ecological validity.

2.3.2. Geometrical aspects

The palpatable part of the stomach was designed to fit into a human simulator mannequin. By basing the design on human anatomy, ecological validity could be ensured thru having palpatable landmarks. Landmarks such as hip bones and rib cages were added through iterations, in order to capture all required anatomical attributes. The silicone abdomen integrated in the final conceptual prototype is shown in Fig. 7., with outer dimensions at 345mm in height and 290mm in width. The figure also shows the placement of sensors.

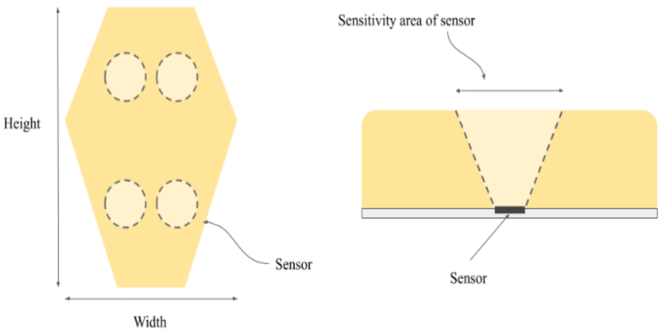

Fig. 7. Illustration of abdomen with sensor placement.

Force applied to the task trainer propagates through silicone, and sensors register it in a greater area than the area of the sensor itself. This effect is also illustrated in Fig. 7. The sensitivity area of the sensors was measured to be approximately 78.5cm^2, while the area of the sensors is 16cm^2. The sensors were placed below 4.5cm of silicone, and approximately 15cm apart.

2.4. Testing the Ecological Validity of the Conceptual Prototype

The final iteration of the task trainer prototype is an independent system, encompassing the critical functions identified through interactions with expert users. Physically resembling a real patient, and with the ability to provide the user with pain feedback the prototype can simulate relevant diseases. To increase the learning outcome, data from practice sessions can be collected to provide each user with feedback on their performance. A conceptual prototype was tested by students and expert users, as depicted in Fig. 8 and Fig. 9. Both were able to diagnose the task trainer for diverticulitis by palpation, and feedback on the experiences were positive. Students were engaged in the test scenario and expert users confirmed the realism of the case. The company associated with the project was also positive to the physical results of the project, and pleased about the positive feedback from users.

As described earlier, ecological validity can be measured based on a prototype’s ability to facilitate training of tasks, by presenting functionality and attributes appropriate for the user to perform them. For the conceptual prototype developed in this project, ecological validity was tested by medical professionals and students. An expert user confirmed the realism of the task trainer and that it had the necessary functionality to facilitate learning. Students examining the task trainer managed to determine the correct diagnosis, which could indicate that appropriate attributes are present.

Fig. 8. An expert user diagnoses the task trainer to confirm realism

Fig. 9. A student practices palpation of the abdomen

3. Discussion and Concluding Remarks

Through a specific case project, this paper gives an exemplification of how user-centered development could leverage prototypes. The case concerns the development of simulation-based training equipment, and more specifically a medical palpation task trainer concept. By medical products mimicking the human physiology, trainees can attempt procedures in both a safe and repeatable training environment. How extensive and to what degree of realism any physical simulator needs to approximate in order to successfully simulate a given task is, however, not evident.

In order to address this challenge, the described project utilized prototyping probes, to elicit functional requirements, as well as to pilot conceptual ideas as training equipment with users. Through these efforts it became apparent that the ecological validity of any evaluated concept needed to satisfy users (and expert users) requirements. This meant, ensuring both task abilities, simulating relevant and needed conditions, tactile and visual resemblance, as well as performance feedback communicated to the trainees.

Insights gathered shows the importance of intentional and reflective prototyping and prototype testing [12]. Specific tests should be performed to explore specific dimensions of the conceptual idea. In the project case, the two levels of abstraction, mainly, prototype attributes and a concept's role in the training curricula needed to be acknowledged. As some prototypes explored specific dimensions of a simulator concept, these were less suited to test and evaluate the intended role of the task trainer. However, both these levels needed to be mapped out in order to ensure an ecological valid concept proposal that had been verified trough several tests with both novice and experienced users. This demonstrates the importance of prototyping continuously, intentionally, and together with users in order to address the challenges concerning early stages of design.

The developed concept is showing potential in training for tactile recognition as well as the motoric skill training. More so the concept is shown to be a good conceptual model to investigate self-directed training concept. We are intending to investigate how pattern-recognition in the data from the simple sensor setup of the prototype could be utilized in providing feedback and debrief information for trainees. Even when only considering the already integrated sensors, position, area coverage, palpation forces, force peaks and timing could inform algorithms to enable not only simple pain point location but also following complete diagnosis scenarios. This is the underlying potential for this prototype system, and for future development.

The main contribution of this paper has been to exemplify how prototypes can aid development of products encompassing complex attributes and user scenarios. This was exemplified by considering the ecological validity of conceptual prototypes, and eliciting requirements in a user-centered and prototype-driven framework with a case project. Determining realistic physical attributes was enabled by discussion with healthcare professionals, through extensive use of prototypes. Furthermore, the paper has showed how user needs and thereby functional requirements could be identified through user interaction and prototyping. The presented case project explains how requirement elicitations was aided by prototypes to make a task trainer with a realistic tactile experience and visual resemblance. Especially in the case presented this was important, as the complexity associated with simulators, and their interaction, makes it difficult to elicit and fixate requirements. Designers investigated not only prototype attributes through user interactions, but also their usability, i.e. the prototype as a concept of training routines and testing of these. By not only investigating user needs, but by being reflective over both physical attributes and the procedure at hand, an ecologically valid task trainer could be developed.

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References

[1] Rex Hartson H. Human–computer interaction: Interdisciplinary roots and trends. J Syst Softw 1998;43:103–18.
[2] Kushniruk A, Nohr C, Jensen S, Borycki EM. From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. Yearb Med Inform 2013;22:78–85.
[3] Sutcliffe A, Sawyer P. Requirements elicitation: Towards the unknown unknowns, 2013, p. 92–104.
[4] Ulrich KT, Eppinger SD. Product design and development. New York: McGraw-Hill/Irwin; 2012.
[5] Jarvis C. Pocket Companion for Physical Examination and Health Assessment. 7th Edition. Missouri: Saunders; 2015.
[6] Leifer L, Steinert M. Dancing with Ambiguity: Causality Behavior, Design Thinking, and Triple-Loop-Learning.Inf-Knowl-SystManag 2011;10:151–73.
[7] Lauff C, Kotys-Schwartz D, Rentschler M. What is a Prototype? What are the Roles of Prototypes in Companies? J Mech Des 2018;140.
[8] Jensen LS, Özkil AG, Mortensen NH. Prototypes In Engineering Design: Definitions and Strategies. 84 Proc Des 2016 14th Int Des Conf 2016:821–30.
[9] Kriesi C, Blindheim J, Bjelland Ø, Steinert M. Creating Dynamic Requirements through Iteratively Prototyping Critical Functionalities. Procedia CIRP 2016;50:790–5.
[10] Auflem M, Erichsen JF, Steinert M. Exemplifying Prototype-Driven Development through Concepts for Medical Training Simulators. 572-578 2019.
[11] Buchenau M, Suri JF. Experience prototyping. Proc. Conf. Des. Interact. Syst. Process. Pract. Methods Tech. - 00, New York City, New York, United States: ACM Press; 2000, p. 424–33.
[12] Houde S, Hill C. What do Prototypes Prototype? In: Helander MG, Landauer TK, Prabhu PV, editors. Handb. Hum.-Comput. Interact. Second Ed., Amsterdam: North-Holland; 1997, p. 367–81.
[13] Menold JD. Prototype for X (PFX): A Prototyping Framework to Support Product Design 2017.
[14] Lim Y-K, Stolterman E, Tenenberg J. The anatomy of prototypes: Prototypes as filters, prototypes as manifestations of design ideas. ACM Trans Comput-Hum Interact TOCHI 2008;15:7:1–7:27.
[15] Maran NJ, Glavin RJ. Low- to high-fidelity simulation - a continuum of medical education? Med Educ 2003;37 Suppl 1:22–8.
[16] Zenios S, Denend L, Brinton TJ, Kumar UN. Biodesign: The Process of Innovating Medical Technologies. Cambridge University Press; 2010.
[17] Hamstra SJ, Brydges R, Hatala R, Zendejas B, Cook DA. Reconsidering Fidelity in Simulation-Based Training. Acad Med 2014;89:387.