User-centered Design in Time and Resource-limited Settings: Enhancing the Usability of 'Hearing for Life' *(HeLe)* Device

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ABSTRACT

Introduction. The Hearing for Life (HeLe) is a novel newborn hearing screening device initially designed according to specifications of clinicians of the Philippine National Ear Institute (PNEI). Unfortunately, targeted end-users, rural health workers, had difficulty using it. This research applied the user-centered design (UCD) methodology involving rural health workers in recommending design, content, and function requirements for HeLe.

Objectives. This study aims to 1) describe how UCD was applied in a time-limited and resource-constrained environment, 2) assess the usability of the design prototypes, and 3) recommend design, content, and function requirements for HeLe.

Methods. This research is a descriptive study using mixed methods. Six rural health units (RHU) involved in the HeLe research program were purposively selected for the study. There were 30 participants included, five health care workers per RHU. Applying the UCD method, the study had three phases: 1) user profiling (where participants accomplished a survey questionnaire, 2) inspiration phase (focus group discussions, workflow analysis, and interviews with a technical expert were conducted), and 3) ideation phase (designing and assessment of prototypes were done).

Results. Participatory methods and structured procedures (i.e., card sorting, MoSCoW matrix prototyping, etc.) were applied to help determine and prioritize user requirements and elicit user feedback. These methods were chosen considering the time and resource constraints in the RHU. The prototype's System Usability Scale (SUS) score (81.94) was higher than the SUS score previously obtained (68) from the older version of the interface. Accuracy, durability, in-app instructions, feedback, and an easily understood interface were the most requested requirements for the telemedicine device. The need for the technology to be aligned with the RHU's workflow and available resources was highlighted in the focus group discussions.

Conclusions. The study documents practices and lessons learned in applying UCD methodology in design and development that have been demonstrated to improve usability of the device. The involvement of the users surfaced in the design, content, and functional requirements which can guide future iterations of HeLe and contribute to better understanding of ways to develop user-friendly telemedicine devices in the Philippines. This paper emphasizes that users should be involved in the entire process and not just recipients of the technology.

Keywords: User-Centered Design, Hearing for Life, digital technology, telemedicine, usability, design and development

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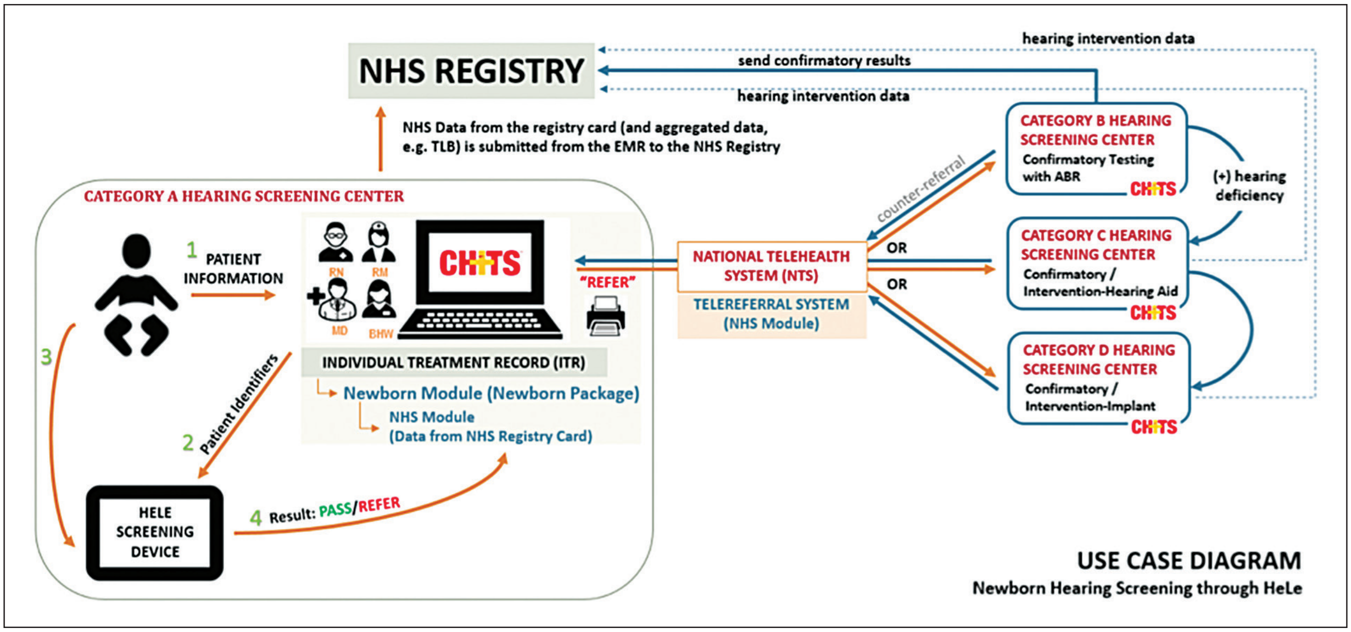


Figure 1. Use case diagram of Newborn Hearing Screening through HeLe as of 2017 (NTHC, 2017).

INTRODUCTION

In 2016, the Philippine National Ear Institute (PNEI) of the National Institutes of Health (NIH) worked on a "Hearing for Life (HeLe)" device which was used in eight municipalities as part of the ongoing research, "Increasing the Rates of Newborn Hearing Screening (NHS) with Novel Technologies and Telehealth" or the "HeLe: Hearing for Life." [1]

The HeLe device was designed and developed by the PNEI with the NIH National Telehealth Center (NTHC), and the University of the Philippines Diliman Electrical and Electronics Engineering Institute (UPD EEEI).[1] The use case diagram of how the NHS works using HeLe is shown in Figure 1.

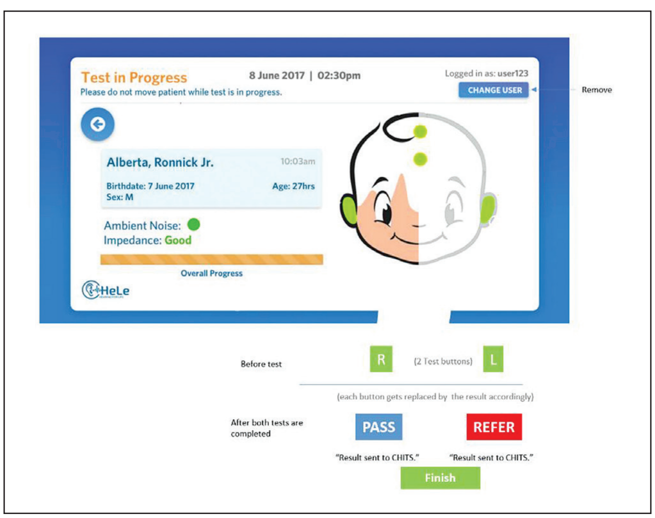


Figure 2. Sample user interface of HeLe device.

The initial prototype (Figure 2) of the HeLe device was designed incorporating specifications defined by experts of the PNEI – audiologists and otolaryngology surgeons (R. Siefert, personal communication, 2017). In the usability assessment conducted by Custodio, they found that the actual RHU health workers were confused about how to use the HeLe device. Some of the notable comments were, "the buttons were not clear" and their functions were "not obvious".[2] Four out of 16 study participants pressed the HeLe device *finish* button after screening a single ear without testing the other ear, which prematurely ended the screening process without testing the other ear. The System Usability Scale (SUS) score of this HeLe UI was 68 out of 100, which suggests a redesign is warranted.[2]

Design is about how things work, controlled, and interact with the user. It is important as it will define whether the product will be usable. When a device doesn't work as users expect them to, it can be frustrating to use.[3]

A good design starts with an understanding of psychology and technology. Most engineers, developers, and designers believe they understand human behavior but blame the users when they fail to use their products properly. It is assumed that reading the instructions would be sufficient for the users to use the technology.[3] A good device user interface could reduce or eliminate use-related hazards, increase correct use and user actions, reduce frustration and irritation from the users, and facilitate acceptance and utilization of technology.[4] The intended user should be able to use the medical device with ease and without making user errors that could compromise medical care or patient and /or user safety.

In developing medical device, target end users (i.e., patients, people with disabilities and/or special needs, and their caregivers) should also be involved and not just the health care providers.[3] Even if the manufacturers and health professionals have considered perceived requirements, end users would still discard the device that do not fit their personal expectations.[5] Active participation of users is important to developing usable and effective devices.[6] One way to do it is through User-Centered Design (UCD) methodology.

UCD, coined by Donald Norman in the 1980s, is a design philosophy that seeks to place the end-user at the beginning and the center of the design process. It aims to put forward guidelines that designers could follow to achieve good usability outcomes and user experience.[3] The methodology involves three phases: 1) Inspiration phase, which involves understanding the people by observing their lives and hearing their hopes and desires; 2) Ideation phase, where the designer must analyze and generate ideas, identify opportunities for design, and test and refine solutions; and 3) Implementation phase, where the technology is carried out to be assessed by the target users in an actual setting.[3]

Applying UCD principles focuses on meeting the needs of the users. Involving the users in the design and development improves the technology because of a more accurate assessment of user requirements and higher level of acceptance. It identifies usability problems and resolves it before being launched. It therefore improves functionality and usability, and increases the likelihood of promoting the intended health behaviors and health outcomes.[7]

Extant literature describes the benefits of user involvement.[3,8,9] However, involving end users in medical device development is still an emerging area of research, especially in the Philippines. In many instances, users are passive participants and mere recipients of technology.[10] Users are only involved when the device will be used in work setting, and has no part in the development or selection of the device.

The Centre for eHealth & Wellbeing Research describes a roadmap comprised of five stages that need to be undertaken by a multidisciplinary team, guided by results of a formative evaluation of each stage: 1) contextual inquiry; 2) value specification; 3) designing prototypes; 4) introduction of the technology; and 5) summative evaluation of uptake and impact.[11]

Two examples of studies using UCD in the design and development of medical device are highlighted in this study. One is "Design and Development of a Telerehabilitation Platform for Patients with Phantom Limb Pain" where users were actively involved in the process and iterations. Requirements for the content and functions were defined by the patients and therapists, who are the immediate users of the output which were translated to the design of the prototype.[12]

Another study, "More Stamina, a Gamified mHealth Solution for Persons with Multiple Sclerosis: Research-Through Design" where researchers identified the needs, barriers, and facilitators for mHealth apps for persons with multiple sclerosis.[13] They followed a user-centered design methodology to create and evaluate a mobile app prototype aimed to help persons with multiple sclerosis.[13] Several usability problems were discovered that guided the iterative design of the solution.[13] Both studies illustrated the benefits of actively involving users in the design process. However, studies using UCD in health technology in the Philippines are still limited.

Applying UCD, this study aims to 1) describe how UCD was applied in a time-limited and resource-constrained environment, 2) assess the usability of the design prototypes, and 3) recommend design, content, and function requirements for HeLe.

METHODS

This research is a descriptive study using mixed methods. It involved **three phases:** 1) User Profiling, which involved administering questionnaires, 2) Inspiration Phase, which involved workflow analysis, participant observation, focus group discussion, and expert interview; and 3) Ideation Phase, which involved design and testing of prototypes.

The self-administered questionnaire was adopted from Venkatesh and was pre-tested to nurses and a doctor from a different RHU before data collection to ensure understandability and clarity of the data gathering tool. This questionnaire was used to obtain demographic data such as age, sex, educational attainment, medical experiences, list of ICTs owned at home or work, level of ICT use by describing how often do they use certain ICTs, and their attitudes towards ICT use where they are asked if they agree or not agree on ICTs relative advantage, compatibility, complexity among others.[14] It was self-administered considering the time and availability of the HCWs. Cronbach's Alpha was processed using Cronbach Alpha (v1.0.5) in Free Statistics Software (v1.2.1).[15] Site visits were conducted to document RHU workflow and interaction of the users to available technologies. The user profile provided insight whether certain demographics prefer particular requirements.

In the inspiration phase, card-sorting activity, adapted from IDEO.org, was used as a priming activity to make the health workers more comfortable in the discussion.[9] List of words were written on the cards and the users were asked to arrange them in order of priority based on how they understood each word. The words used in the activity were: Training, Instructions, User-friendly, Simplicity, Accuracy, Understandability, Feedback, Readability, Speed, Security, Error-detection, Privacy, Consistency, Durability, Brightness, and Color. There were no correct or wrong answers in arranging the cards, what mattered was how the participants explained how the cards were sorted.

Guided discussions were then conducted to elicit requirements. Requirements were ranked using the MoSCoW (Must, Should, Could, and Won't Have) prioritization matrix.[9] 'Must Haves' are the important and vital requirements that the HeLe device must have; 'Should Haves' are important requirements but not vital; 'Could haves' are wanted or desirable but not important; and 'Won't have this time' are requirements that are not important and not vital. Technical specifications from an audiologist in the regional hospital in Iloilo also helped ensure the requirements and execution of the HeLe device are aligned with their clinical practice guidelines.

Insights gathered from the user profile and inspiration phase guided the design prototypes for the ideation phase. In the ideation phase, three low-fidelity prototypes, in the form of paper drawings and cut-outs, were shown to the HCWs. They walked through each of the pages and were asked to comment or suggest in terms of design, content, or function, which of the designs were preferred and not preferred. They were also asked the level of priority of each requirement. Frequently requested must-have and should-have features were noted and translated to design solutions. After incorporating the feedback, it was rendered to a mobile version mock-up (medium fidelity prototype) and deployed in a mobile tablet with dimensions almost similar to the HeLe device's. Adobe XD version 17.0.12.11, a free Adobe software, was used to develop the mock-ups. This software was used as it is free and readily available.

A task list was prepared to ensure the users will cover all steps. Successful tasks, failed tasks, common errors, and feedback by the users were documented and analyzed. After completing the task lists, System Usability Scale were administered to gauge the system's usability level.

Six rural health units (RHU) involved in the HeLe research program were purposively selected for the study. Three HeLe target sites in Iloilo (Igbaras, Tigbauan, and Tubungan); and three non-HeLe target (Miagao, San Joaquin, Guimbal) were selected. The non-HeLe target sites were purposively selected as they are in close proximity tof the three target sites and belong to the same district. Thirty participants, i.e., five (5) RHU health workers led by their Municipal Health Officer (MHO) per RHU, were recruited in the study. The other four HCWs were selected by the MHOs based on availability and role in the RHUs. This satisfies the sample size recommendations for the different phases of the research in conducting user research methods striking a balance between rigor and practicality.[16] Sample size should be 12-20 participants for user research methods, 15 to 30 participants for card sorting activity, 4 to 12 participants for focus group discussion. Furthermore, it satisfies Faulkner et al.'s recommendation suggesting that 15 people theoretically provide the best possibility of detecting user interface design problems with an average of 97% while limiting the number of resources required.[16] In addition, an audiologist from the government Regional Hospital was interviewed to get technical input on the functional requirements of an innovative NHS device. These were reviewed and matched with the user requirements identified by the representative users.

This study protocol was reviewed and approved by the Research Ethics Board (REB) of the University of the Philippines Manila.

RESULTS

Application of UCD in the HeLe UI design

Phase I. User and Rural Health Unit Profile

Generally, the selected RHUs have access to electricity, internet connectivity, and mobile data but with weak connections in sites relatively farther from the city. The RHUs have at least one desktop and laptop computer; all are EMR-enabled. Four of six RHUs have lying-in clinics but only two that are actively providing birthing services and screening for genetic metabolic anomalies among newborns. The other two sites were under renovation and did not attend to parturient mothers at the time of this study. Notably, none of the six sites screens newborns for hearing problems using a hearing screening device. The medical doctors described their newborn hearing screening method as the "Baah test", where they would produce the "Baah" sound to the newborn to elicit a reflexive response and determine if there is a hearing problem.

There were 30 respondents composed of six (6) medical doctors, eight (8) nurses, and 16 midwives (Table 1). The average age of participants was 43.8 (±10.1) years old, with a range of 25 years old to 63 years old. More than half of the participants are in the older population and above 46 years old. Years of medical service range from less than a year to 33 years; the majority have worked for more than 20 years. (Three of these 30 health workers dropped out of the two-month long UCD process when they resigned from the RHU within the duration of this study. Hence, the change of 'respondents' data reported for subsequent questions.)

ICT Ownership and Use

Most of the participants have access to desktop and laptop computers at work in almost the same proportion (22 or 73.3% and 23 or 76.7%, respectively) (Table 2). All doctors have access to laptops both at work and at home. Among all respondents, desktop and laptop computers were reported to be used almost every time ($\bar{x}$=3.57 and 3.90, respectively). Noteworthy is that even with the passage of the law requiring hearing screening among all newborns, the health workers in these Rural Health Units reported never using any newborn hearing screening device nor having access to it at work.

HCWs strongly agree that using ICT has a relative advantage (Table 3) and has the highest score among purported benefits of ICT listed in the survey (with a mean score of 4.30; the highest mean score is 5.0). Similarly, participants agree, especially the doctors (score of 4.67), that ICT enhances their job effectiveness and improves the quality of medical work (Table 3, RA2). Furthermore, they also agree

Table 1. User Profile of the Study Participants from the Six Municipalities in Iloilo (n=30)

	n	(%)
Profession		
Midwife	16	(53.3)
Nurse	8	(26.7)
Doctor	6	(20.0)
Total	30	(100.0)
Educational Attainment		
College	24	(80)
Post-graduate	6	(20)
Total	30	(100.0)
Age (years)		
25 and below	1	(3.3)
26-35	8	(26.7)
36-45	5	(16.7)
46-55	14	(46.7)
Above 55	2	(6.7)
Total	30	(100.0)
Mean	43.8	(± 10.1)
Monthly Income (Php)		
No data	3	(10.0)
<10,000	1	(3.3)
10,001 - 15,000	11	(36.7)
15,001 - 20,000	6	(20.0)
20,001 - 25,000	3	(10.0)
>25,000	6	(20.0)
Total	30	(100.0)
Mean	25,661.96 (± 21,207.23)	
Medical Experience (years)		
5 and below	4	(13.3)
6 to 10	7	(23.3)
11 to 15	7	(23.3)
16 to 20	4	(13.3)
Above 20	8	(26.7)
Total	30	(100.0)
Mean	14.9	(± 8.18)

that ICT is entirely compatible with their current situation (Table 3, CT8).

Complexity had the lowest score among all components, wherein *using ICT does not require much mental effort* garnering the lowest score (mean score of 2.90). Trial-ability and observability scored 3.71 and 3.78, respectively. These translate to respondents having equivocal views about these characteristics of ICT innovations.

Inspiration Phase

User Requirements

There were 27 user requirements elicited from the focus group discussions in the six sites (Table 4). These were ranked based on the MoSCoW prioritization matrix and categorized according to design, function, or content. The most requested requirements for a telemedicine device that the users cited include accuracy, durability, instructions, feedback, and should be easy to understand. Accuracy was defined by the users as the ability of the device to give correct results especially since they are dealing with lives of the newborn, and erroneous results could lead to detrimental effects in the long run. Durability referred to the ability of the device to withstand continued use. One participant said, "it's nice and all, but what would I do with it if it gets damaged easily", pertaining to durability. Feedback was understood as the ability of the users to send comments or suggestions to the institution who developed the device. Finally, easy to understand meant the users should be able to easily know how to operate the device.

Training, instructions, and user-friendliness were also listed at the top of the list during the card sorting activity. They explained that it is vital for them to know how to use the device through proper training and instructions. Furthermore, one participant mentioned that one of the possible reasons technology is not successful in their RHU is because their previous experience with other medical devices was not user-friendly. Five respondents (n=5) across six sites reported that they would use the device if it were user-friendly especially since most of them in the RHU are

Table 2. ICT Ownership and Level of Use of the Study Participants

ICT	H	W	B	N	T	Level of Use[1]	
Desktop	0	22	3	5	25	3.57	Almost Every time
Laptop	4	8	15	2	28	3.90	Almost Every time
Laptop (Touch)	3	4	5	18	12	2.74	Occasional
Basic Mobile	12	1	5	12	18	3.24	Occasional
Mobile Phone (Touch)	14	0	15	1	29	4.79	Every time
Tablet (Touch)	8	4	4	14	16	2.84	Occasional
Digital Camera	5	3	3	19	11	2.58	Rarely
Internet	1	6	17	6	24	4.10	Almost Every time
PDA	2	3	1	24	6	2.14	Rarely
NHS Test	0	0	0	30	0	1.58	Never

Legend: 1.00 – Never; 2 – Rarely; 3 – Occasional; 4 – Almost Every time; 5 – Every time; Cronbach Alpha = 0.83; H – Home, W – Work, N – None
H – Home Only; W – Work Only; B – Both Home and Work; N – None; T- Either Home/ Work

not technologically adept. They do not have someone to ask how to use any medical device.

The card sorting activity also helped the users explain features that are important to them. One participant mentioned that, *"Accuracy is important, especially from our experience before. The device did not give accurate results, and since then, we questioned the credibility of the device and ended up not using it"*. One suggested a way to ensure this is to have regular device calibration.

Durability was a significant consideration because of their experience with the previous technology that broke quickly. It was also suggested to have service centers near the region to promptly repair devices when damaged. Meanwhile, *instructions* are required by the health workers since not everyone was trained to use the HeLe device. Apart from instructions, quick access to a manual in the device and a hard copy should be made available. The *feedback* requirement was elaborated as the: 1) confirmation that the device received their action (i.e., vibrate, sound); and 2) prompt or warning sign when they are doing the wrong thing or pushing the wrong button. They also want to add *prompts* when the device remains idle for a particular time, which might signify that the health worker is struggling with what to do next. Another must-have requirement mentioned is that it should be easy to understand, such as in smartphones which entails minimal to no training to use. The device can also be easily understood by making the content and steps very straightforward.

Noteworthy, they require the device to have print functionality in all sites. They justified that printed results are still significant even if the Department of Health (DOH) pushes for paperless systems. They still need to attach printouts of test results in medical records, or printed copies are required when referring the patient to the hospital or any referral facility.

Feedback from the low fidelity prototyping affirmed the critical requirements discussed by the user from focus group discussions. In four of the six RHUs, the group preferred the third prototype that focused on simplicity since it is straightforward to understand. There were only a few steps to perform the intended action, and it was easy to understand.

Table 3. The Attitude of Participants towards ICT (Adopted from UTAUT Questionnaire – 5 Point Likert Scale)

Questions[1]	UTAUT Rating			
	Doctor[2]	Midwife[2]	Nurse[2]	Average
Relative Advantage	4.54	4.18	4.35	4.30
RA1. Using ICT enables me to accomplish a medical task more quickly	4.50	4.25	4.38	4.33
RA2. Using ICT improves the quality of medical work I do	4.67	4.25	4.25	4.33
RA3. Using ICT makes me do my medical work easily	4.60	4.25	4.38	4.34
RA4. Using ICT makes me improve my job performance	4.50	4.13	4.38	4.27
RA5. Using ICT enhances my effectiveness in my job	4.67	4.25	4.50	4.40
RA6. Using ICT gives me greater control over my work	4.33	3.94	4.25	4.10
Compatibility	4.67	3.96	4.38	4.22
CT7. Using ICT increases my work productivity	4.67	4.13	4.50	4.33
CT8. Using ICT is entirely compatible with my current situation	4.67	3.80	4.25	4.10
Complexity	3.83	3.37	3.71	3.56
CX9. I think the ICT I used fits well with the way I like to work	4.83	3.87	4.38	4.21
CX10. Using ICT fits nicely into my work style	4.50	3.53	4.13	3.90
CX11. I believe that using ICT is not complicated[3]	3.33	3.06	3.50	3.23
CX12. Using ICT does not require a lot of mental effort[3]	2.67	3.00	2.86	2.90
Trial-ability	3.75	3.69	3.75	3.71
T13. Using ICT is not often frustrating[1]	3.67	3.31	3.63	3.47
T14. I believe that it is easy to make ICT do what I want it to do	3.83	3.88	4.00	3.90
T15. Learning to operate ICT is easier for me	3.83	3.63	3.63	3.67
T16. I have had a great deal of opportunities to try ICT applications	3.67	3.93	3.75	3.82
Observability	3.73	3.81	3.75	3.78
O17. I know where I can go to try out ICT satisfactorily	4.00	3.44	3.63	3.60
O18. I always try out ICT applications before using it	4.00	4.07	3.63	3.93
O19. I use ICT on a trial basis enough to see what it could do	3.80	3.87	3.63	3.79
O20. I do not have to take very much effort to try out ICT	3.17	3.25	3.63	3.33
O21. I have seen what other hospital staff do with ICTs	3.83	4.00	4.00	3.97
O22. In the hospital, I see ICT being used for many tasks	3.83	4.06	4.25	4.07
O23. ICT is very visible in the hospital where I work	3.50	3.87	3.63	3.72
O24. It is easy to observe people using ICT in the hospital	3.67	3.94	3.63	3.80

[1] *Cronbach alpha = 0.8488*
[2] *Legend: 1.00-1.80 – Strongly Disagree; 1.81-2.60 – Disagree; 2.61-3.40 – Neither; 3.41-4.20 – Agree; 4.21-5.00 – Strongly Agree.*
[3] *Questions were negatively phrased, and the results were processed inversely*

One participant emphasized regarding having instructions in place stating that, "*Design three is easy to understand, but it would be better if there are instructions or warning, especially if you are doing it wrong."* In three sites, users emphasized the importance of instruction present in prototype 2, but with a certain simplicity level similar to prototype 3.

Technical Inputs from Clinical Audiologist

In a separate session, a clinical audiologist in the Regional Hospital in Iloilo was interviewed to get technical specifications in the HeLe device. The clinical audiologist is a health care professional that can competently perform audiologic evaluation and audiologic habilitation. In terms of *design*, the clinical audiologist highly recommended a user-friendly and easy-to-understand UI considering the age group of health workers in the RHU. It was also observed that RHU staff are no longer open to learning complicated things or are often afraid to handle a device. Moreover, text size and buttons should be large enough to be readable, and instructions to perform the required task should be minimal and not text-heavy. Based on these inputs, the prototype was designed with readable font styles, larger buttons, and instructions composed of fewer steps.

Regarding content, the clinical audiologist suggested using the standard terms for the results, i.e., "Pass" and "Refer." These are the standard terms in their practice described in the Newborn Hearing Screening Manual as most hearing devices are just screening tools and need referral for further confirmation. Moreover, the patient data to be collected should be based on the requirements specified in the Newborn Hearing Screening Manual and reports to claim payment for rendering the Newborn Care Package of the PhilHealth. A copy of the forms were obtained and adapted in the print-out interface. Also, following the manual

Table 4. List of User Requirements and design solutions taken (n=27)

User Requirements	Priority	Class	Action Taken
1. Accuracy	M, S	F	Added "Maintenance Check" or "Diagnostic Check" function; Visual prompts to remind of monthly/ regular maintenance or diagnostics and month last checked; Suggest to NTHC regular calibration or testing of the device
2. Durability	M, W	F	Endorsed to NTHC
3. Instructions	M, S	D, C	Instructions and a manual were added in the design
4. Feedback to confirm correct action	M, S, W	D, C, F	Visual prompts / Feedback; Show progress of test
5. Error-detection	M, S	D, C, F	Visual prompt / Feedback; Instructions how to correct the action Inactive buttons
6. Simple and easy to understand	M, S	D, C	Use of simple and straightforward terms
7. Security of data	M	F	Added sync function to EMR; Suggest to NTHC easier method to back up EMR data
8. Training	M, S	C, F	Suggest to NTHC; Manual readily available in device; Accessible video instructions
9. Complete functionality	M	F, C	Incorporated Technical Expert inputs (e.g., content, workflow); Incorporated standard DOH/ PhilHealth forms
10. Interpret results for the users	M	F, C	Incorporated in the design: "Pass" or "Refer"
11. Portability	M, W	F	Endorsed to NTHC
12. Print-function	M	F	Added print function button; Suggest to NTHC
13. Privacy and Confidentiality	M	D, F	Sign in and sign out; Suggest to auto sign out during idle time
14. User-friendly	S	D, C, F	Simple and straightforward
15. Stand-alone	S	F	Endorse to NTHC; Placeholder for sync data
16. Speed	S	F	Endorse to NTHC
17. Visual Aesthetics (i.e., colorful)	W	D	Documented for future iterations
18. Brightness	W	D	Added function to adjust brightness and other device settings
19. Cost-effective	W	F	Documented for future iterations; Suggest to NTHC
20. Readable font	M, W	D	Use of larger fonts for important information
21. Access to maintenance	M	N/A	Suggest to NTHC
22. Able to connect to internet	M, W	F	Device is already wifi ready
23. No recurring data	M	C	Auto complete for data already gathered
24. Not electric dependent	M, S, W	F	Suggest to NTHC
25. Responsive to touch	M	F	Suggest to NTHC
26. Interoperable	W	F	Documented for future iterations; Suggest to NTHC
27. Messenger function	W	F	Documented for future iterations; Suggest to NTHC

Legend: M – Must Have; S – Should have; W – Could-have or wont-have; F – Function; D – Design, C – Content, N/A – Not applicable and audiologist's recommendation, the design reinforced the users to test thrice for "refer" results.

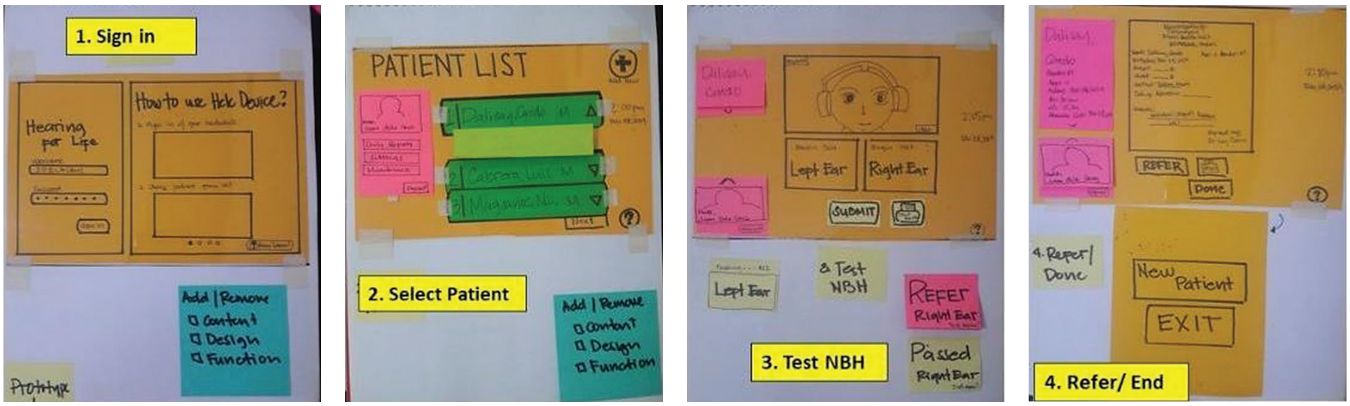
For specific *functions*, the clinical audiologist emphasized accuracy. The device should be "*unquestionably accurate*." It will defeat the purpose of everything if the device is not accurate. In addition, the workflow on the Manual of Procedures for Newborn Hearing Screening Program should integrate into the UI design to guide the HCWs to follow specific required steps. Printing of the referral form, patient registry forms, and results form with the device ID should also be added as these are needed for PhilHealth to reimburse the RHU for the NHS test.

Ideation Phase

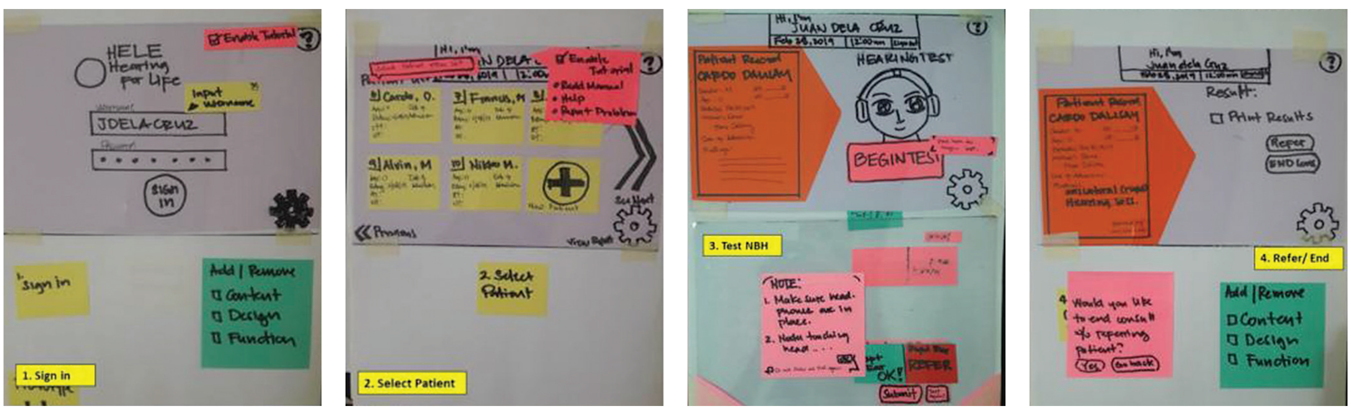
Low Fidelity Prototype

Three design paper sketches were prepared and presented to the study participants to maximize the site visits (Figure 3).

A. Protype 1 – Training Requirement



B. Prototype 2 – Instructions Requirement



C. Prototype 3 – Simple Requirement

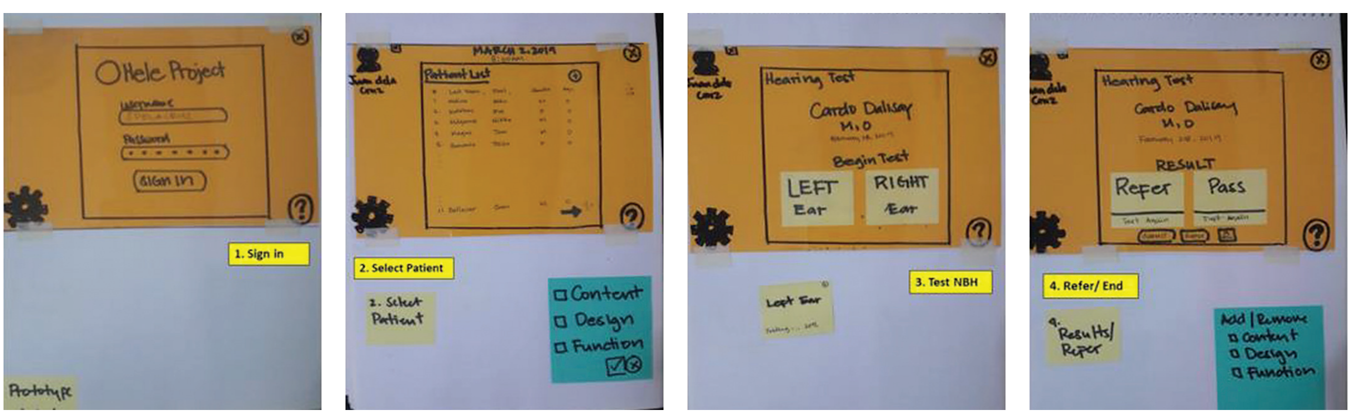


Figure 3. Sample low-fidelity prototype.

All prototypes shared a common workflow and pages to perform the newborn hearing screening procedures, as follows:

1. **Sign in page** – This serves as the home page and user authentication page.
2. **List of patients** – This page is where the user can see all patients in queue and select which patient to test for NHS. Each prototype contained varying layout of the list and content being displayed.
3. **Newborn hearing screening** – This page is where the user can perform the actual test.
4. **Referral or Printing of the results** – This page is where users can review the results for referral or printing. A test case for newborns with hearing problem was used for all prototypes.

Each design prototype has a distinct feature highlighting the different requirements from ideation phase. The first prototype focused more on the training requirement (Figure 3A). Prior to signing in, the interface contains reference materials and video resources how to use the device. In-app video instructions on how to place the device to the newborn and help button were made very visible across the interface. This attempted to address the need for the user to be trained on how to use the device before actually using it. The second prototype attempted to address the in-app instruction requirement (Figure 3B). This was achieved by providing visual prompts and feedbacks in every page in the application. A pop-up instructions were shown for each step to guide the user what to do. The third prototype highlighted simplicity (Figure 3C). There were no instructions or visual prompts. Other information and buttons were removed. And the screen has a consistent and default sections all throughout the steps.

The participants were asked to choose among the prototypes and to pinpoint specific features they wanted to be improved. Feedback on the prototypes was integrated to the Medium Fidelity Prototype.

Medium Fidelity Prototype

The medium fidelity prototype (Figure 4) was developed using Adobe XD version 17.0.12.11, a free Adobe software to show detailed graphics, placeholders, and actions of the corresponding buttons and functions. This prototype was presented on a tablet device with almost similar dimension to the actual HeLe device used.

Subsequently, a Concurrent Think-Aloud (CTA) activity was used where the participants narrate or verbalize their thoughts while interacting with the HeLe UI in the tablet. The activity allowed the researcher to understand what the users were thinking about and how the users behaved with the proposed design, and in the process continuously identify additional problems, and requirements in terms of design, content, and function that had not been detected in the inspiration phase or in the low-fidelity prototype testing. List of tasks to accomplish were provided to ensure all functions are covered. The tasks emphasized four major activities: 1) Sign in, 2) Select Patient, 3) Perform Test (left ear and right ear), 4) Submit results. Specific details on how and where to perform the tasks were not included. Common user errors and problems with the design such as the font styles, button sizes, etc. were documented. The average time elapsed was also computed and described. Activities with relatively low effectiveness (accomplished) and efficiency (time elapsed) scores were investigated. All responses from the evaluation of low-fidelity and medium-fidelity prototypes were extracted, and patterns were identified, meaningfully interpreted, and translated to design, content, or functional requirements.

System Usability Testing

Self-administered System Usability Scale (SUS) questionnaire were distributed to the participants immediately after the CTA to assess the medium-fidelity prototype. The SUS is a simple, ten-item Likert scale measuring subjective assessments of parameters of usability. SUS score is calculated by summing the score contributions from each item (ranges from 0 to 4). The score contribution for items in odd numbers is the scale position minus 1. For items in even numbers on the other hand, is 5 minus the scale position. Then multiply the sum by 2.5 to get the overall value. SUS scores range from 0 to 100. This study followed Bangor et al., category and set 60 (marginally unacceptable) as a cut-off score.[17] The score of the Medium Fidelity Prototype obtained from 27 respondents was 81.94 (±14.60). This is interpreted as acceptable, meaning most will likely not have usability problems and merit no further iterations.[17] The lowest score obtained was 57.5 given by two midwives while the highest score was 100 from three doctors, one nurse, and one midwife.

The average time elapsed to finish all the NHS tasks was 173.19 (±54.43) seconds, or 2 minutes and 53 seconds (Table 5).

The activity on the *patient list* page was relatively fast. Twenty-six (26) out of 27 performed the task correctly without external help from the researcher. The *users greatly appreciated the search button*. They specifically requested this function when the Low Fidelity Prototype was being discussed. In the medium fidelity prototype design phase, the search buttons were just placeholders and not yet functional.

The users took most of their time on the NHS perform test page, 80.44 seconds (±26.49) as this page involves several steps in order to complete. Most users had difficulty signing into the device; 10 succeeded only after several trials and errors. HCWs spent an average of 80.44 (±26.49) seconds to finish the activity. However, two health workers took more time than others because they got confused about starting the test and which step to do first. Nevertheless, 21 health workers completed the task without help from the researcher.

Six users appreciated the instructions and carefully read them as a guide. Two other health workers thought the instructions were buttons to tap.

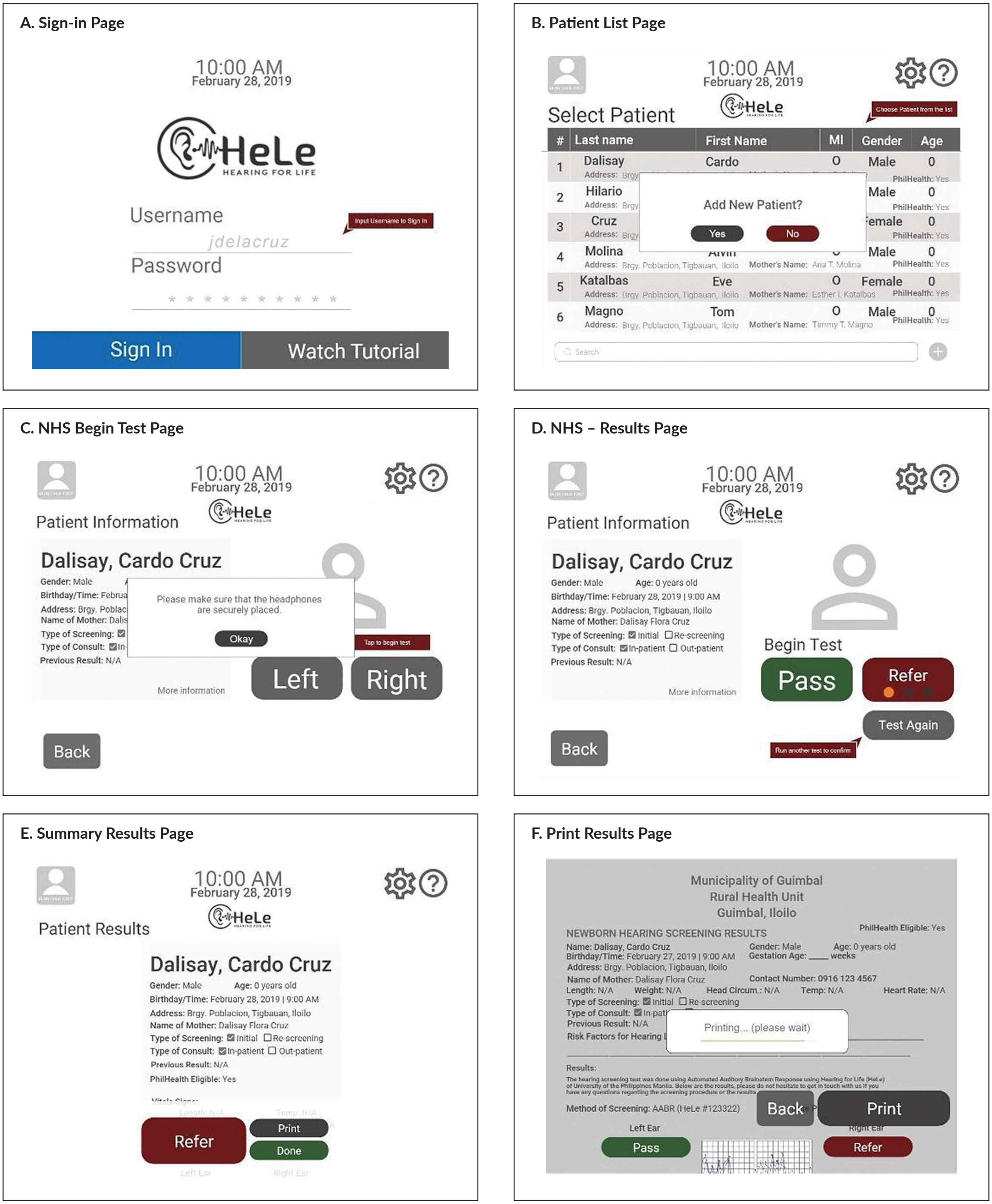


Figure 4. Medium fidelity prototypes of the HeLe user interface.

Table 5. Summary of Task Accomplished and Time Elapsed

Tasklist	Done†	N	Time (in sec)
1. Sign in Page			**28.52 (±13.19)**
- Tap username input field	50%	**10**	34.9 (±15.47)*
- Tap keyboard	100%	**17**	24.76 (±10.37)*
- Tap password input field			*p*-value: .026‡
- Tap keyboard			
- Tap sign in			
2. Select Patient			**9.93 (±15.22)**
- Tap patient "Cardo Dalisay"	50%	1	79
	100%	26	7.27 (±6.55)
			p-value: .026‡
3. Perform test			**80.44 (±26.49)**
- Tap "Left" button to start test	50%	6	95.33 (±27.74)
- Tap Okay to confirm test	100%	21	76.19 (±25.19)
- Tap again "Left button"			*p*-value: .60‡
- Tap "right" button			
- Tap "test" again (2 of 3)			
- Tap "test" again (3 of 3)			
- Tap submit			
4. Print / Submit Results			**54.30 (±24.30)**
- Scroll to check results	50%	8	57.50 (±26.33)
- Tap Print	100%	19	52.95 (±24.02)
- Review result' s print preview			*p*-value: .089‡
- Tap print			
- Tap done			
- Tap log out			
Total Elapsed			173.19 (±54.43)

† *0% – Fails to complete the task correctly, gives up, or succeeds only with an assist from the moderator; 50% – succeeds, but in a round-about way, making errors, needing to back track or using on-line help; 100% – succeeds quickly, following the route the designers intended.*

‡ *alpha at .05*

DISCUSSION

Lessons from RHU and User Profile

The user profile of the RHU (53.3% Females, 46.7% belonging to 46-55 years old) reflected the typical age and gender distribution in most RHUs in the Philippines. The individual characteristics are important to note as this could be potential moderators of adoption.[14] For older adults, according to Berkowsky et al., their self-assessed abilities on computer or internet skills could be a predictor for adoption.[18] The majority of the older health workers expressed their disinterest, thinking it is complicated and younger health workers are there to operate the medical devices.[18] This might not necessarily reflect sentiments of all older population as the sample size is limited. However, the participant observation suggests that younger health workers primarily handle tasks involving computers or other technology-based activities. This supports SAQ suggesting that most HCW perceived technology as always complex. Using ICT does not require mental health effort (2.90) scored the lowest. Participants, especially those from older population, claim they are already too 'non-techie' and old to understand or learn to understand new technology. Ironically, these same HCWs also reported having access and using other forms of ICTs (i.e., smartphones, computers) in their daily lives.

Examined further, HCWs complained that as much as they wanted to use technologies, they perceived EMR as additional work. They have to do both the electronic and manual encoding in documenting patient information and preparing and submitting aggregated reports, respectively. Berkowsky et al. support this, suggesting that older adults' confidence in learning the technology and the perceived value and impact on the quality of life were the strongest predictors of a willingness to adopt a technology.[18]

Understanding the fears and concerns of HCWs through user profiling is as critical as developing the ICT itself. HCWs have different fears and perceptions about technology that could be addressed with adequate education and support.

Inspiration phase

The Card Sorting Activity helped initiate the conversation with the users. The list of words allowed the users to verbalize what they wanted in the device and how much they value each requirement. The activity somehow provided them the concepts to describe the design, content, and functions they want in the user interface. It enabled discussions to flesh out their attitudes, desires, and fears interacting with technology. Further, the activity is easily understood by both the research participants and researchers, easy to prepare, and affordable, thus accessible to those in low-resource settings.[19]

Focus group discussion had been an efficient way to extract information and understand the design creativity, desired and actual user experience, and usability of the Low and Medium Fidelity Prototypes. It was also ideal in order not to disrupt their work in the RHU. The choice was found to be beneficial to the data collection. Getting similar sentiments from colleagues helped them articulate their feedback on the technology.

But as recommended by the Interaction Design Foundation, the user interviews or focus group discussions were treated as contextual. Sometimes it is not what the people say they will do, and people may have memory issues and thus could not recall details as clearly.[19] The interviews can serve as a starting point to examine the users' problems, fears, goals, user experiences, the usability of the product, etc. They were rarely used to solely achieve a finished output. Users, after all, are not designers, but they can at least probably suggest design ideas.

Usability in this paper is defined as how well users can use the technology to achieve a defined goal effectively, efficiently, and satisfactorily. This is important even more in medical devices where the life and/or quality of life of a patient is on the line.

MoSCoW prioritization matrix was helpful as it made clear to the HCWs that some conditions may not be incorporated in the design, considering there are limitations in terms of time and budget. The matrix allowed discussing among themselves what they felt were critical and needed by their RHU. Inputs from a clinical audiologist were beneficial, especially in the process and content, as most of the HCW in the SAQs results have no access to NHS devices. This could also be done after designing the prototypes by letting the experts walk through the prototype and looking for issues with the design, accessibility, and usability of the product.[19]

User Requirements

The series of participatory methods and structured procedures surfaced a total of twenty-seven user requirements. Apart from prioritization, these requirements were classified according to design, content, and functional condition.

Design

Nine of the 27 user requirements raised during the FGDs are design-related (Table 4) and it reflected the fundamental concepts of Norman, specifically affordance, constraints, signifier, and feedback.[3] A good device user interface could reduce or eliminate use-related hazards that could compromise medical care, increase correct use and user actions, minimize user frustration and irritation, and facilitate technology acceptance and utilization.[4]

According to Norman, affordance refers to the relationship between a physical object and a person, the relationship between the properties of an object, and how the thing could be used.[3] It was observed during the CTA when users easily associated the icon's help, settings, and exits to their potential use. Affordance was also articulated in the results when a participant suggested using the tabular format for the patient queue to "resemble their existing EMR" since they are more accustomed to that type of presentation.

Constraints, which refer to cues limiting possible actions, were found helpful in ensuring they do the tasks. In the Low Fidelity Prototype, the health workers preferred the prototype that disabled buttons to proceed to submission unless all steps had been conducted thoroughly.

Signifiers were incorporated in the design in the visual prompts, color codes, shapes, and font styles. Its purpose is to guide the users on what to do in the particular page or perform their intended tasks. Instructions were also a form of a signifier, although a more deliberate one.[20] This was requested by the users in case they forgot what to do on a specific page. For example in the case of the two HCWs who were confused on how to start the test, a signifier in a form of an instruction would be helpful to prompt them what they should do next. It assured them that they were using the device correctly and improved their willingness to use it. As emphasized by Berkowsky et al., a users' lack of confidence in using the device could be a barrier in technology adoption.[18] Having these layers of safety nets for the users convinced, even the older HCWs, that they can use the device. However, it should be noted that these instructions should not be obscuring nor cause further confusion on how to interact with the device. Use of different colors or opacity for the instructions could reduce this confusion.

Signifiers were also used to incorporate the suggestion of the clinical expert in conducting NHS. Signifiers in the form of three colored dots were displayed on the testing page to inform the users to re-test three times the patients who were reported to have a hearing problem. While signifiers were beneficial, it was also important to test them to ensure they are intuitive and useful to the users. Similar to the different layouts, shapes, and visual presentation of the information tested during the paper prototype testing, signifiers if resource permits should also be meticulously tested to enhance usability of the device.

Finally, another recurring requirement for the HCWs is to have feedback (i.e., sounds, visual cues, vibrations) to notify the users that they are doing the tasks correctly. During the Think Aloud activity, one participant religiously read everything that flashed on the screen. He also appreciated that the device displayed 'checking nodes' and 'testing' upon pressing the test button. Participant was relieved that the device received the action and indicated the need to wait while the test was ongoing. Feedback was significant so that the users would know that the device acknowledges the users' action (e.g., they triggered the start of the test) and need to wait for the test to be completed.

User interface design also involves making the interface visually appealing, influencing proper use, reducing error, and improving the user's willingness to use the device.

Content

Nine of the 27 user requirements were content-related. The content should have all the essential data based on national or international standards, instructions, and even content related to decision support.

Preparing and submitting reports to different government offices during the inspiration phase is a recurring concern for HCW. It entailed additional work for the HCWs, especially since various offices require differently formatted yet similar reports. HCWs wanted to be assured that the data gathered in the device were complete data sets needed to submit information to the DOH. Input from the clinical expert regarding the essential data by the national government helped in completing this requirement.

All this content had to be organized and displayed in a not confusing or overwhelming manner. The Interaction Design Foundation (IDF) emphasized find-ability to be an essential concept to ensure a good user experience. This refers to the idea that "the product and the content within them should be easy to locate or find".[19] Different font styles, text boxes, and other visual elements aided the users in locating only the needed content for the specific task. This aligned with Wong's study that recommends the reduction of *"visual clutter"* to not compete with users' limited attention. Further, Wong emphasized the need to limit only to necessary components for the current tasks to provide clear, visible, and unambiguous means of navigating or understanding the content.[21]

But clarity does not mean empty UI. Alexander and Staggers contradict that it is more optimal to have dense screens that include all pertinent information to minimize unnecessary movements between screens to search for information.[22] FGDs, prototype testing, and participant observations helped strike a balance between complete and precise by understanding how the health workers make their decisions and the information necessary displayed on every screen or in a particular task.

Having all the contents needed is not enough; how it will be presented and when it should be displayed should also be considered.

Function

Twenty (20) of the 27 requirements were function-related. There were common themes in the operations requested by the health workers across all sites. Mostly these were accuracy, durability, built-in instructions, ready-to-use, security, confidentiality, and the *print* function.

This study elucidated the importance given by HCWs for the credibility of the device they are using. During the FGDs, they emphasize that the accuracy of the information must be, by no exception, accurate. They also noted the need for the device to be built to last. The machine needed to remain stable even after several uses, especially in isolated communities, to access service centers, and communicate with the project proponent. This is especially cited since RHUs serve geographically isolated communities, to access service centers, and communicate with the research proponents for device repair is cumbersome. Credibility influences good user experience, according to IDF. This involves *the ability of the user to trust in the product provided, not only that it does the job it is supposed to do, but also that it will last for a reasonable amount of time and the information provided with it is accurate and fit-for-purpose"* [19] This study found similar findings and reported them as the top requirement.

Functions related to training and ease of learning the device were also a primary must-have requirement by the HCWs. Since most health workers expressed that they are not adept with technology, they want the HeLe device to be easily understood and not require too much mental effort to use it, on top of the demands of everyday work. This relates to what Berkowsky said in the earlier discussion that confidence to use predicts the willingness to use technology.[18] HCWs explained that having these instructions are significant considering the fast turn-over rate of HCWs, especially among the younger ones. However, on-site or regional training events are costly and require the HCW to leave the RHU for a certain period, which in turn slows down health care services. Moreover, when HCWs trained on the technology leave the RHU, the knowledge leaves with them. Typically, instructions are not being cascaded to the remaining HCWs. In-app instructions and quick access to a guide on using the device or software are standard features in most commercial devices or digital phone applications. This feature might be helpful to HCWs.

Another requirement elicited is having a *print* function in the device, requested by almost all sites. Health workers explained that although the government's thrust is to use an EMR, they still need to have printed results to refer patients until the promised service delivery network is well established. It is a vital health service to screen newborns for hearing problems. Understanding this is important to ensure that the technology to be introduced is aligned with their workflow.

With this requirement, we could infer that compatibility and facilitating conditions, described by Venkatesh in UTAUT, should be considered in designing the technology. The UTAUT underscores the importance of compatibility of the device with service delivery to facilitate technology adoption.[14] Facilitating conditions means that the introduction of the innovation should consider availability of resources (i.e., equipment, infrastructure, etc.) of the target user and if they are capable of implementing it. These are often missed when developers do not profile their target recipients. One participant articulated it further being a recipient of many projects in the past stating "these projects and policies imposed by national government have failed because they never consider the conditions in the grassroots. For example, electricity, which is necessary for their EMR, was erratic in the locale".

Fleshing out all these requirements at the beginning of the design and development allows more room to accommodate the requirements with lesser resource implications.

Lessons during the ideation phase

Paper prototypes were useful, economical, and easy to revise on the spot. IDEO and Smaradottir also describe this as an efficient way to describe suggestions for functionality and user interface.[19,23] Moreover, providing several comparative designs during the Low Fidelity Prototype FGD helped elicit what the users want and do not want in a user interface. It also helped narrow down design choices on specific interfaces that appeared to be problematic for the users. This also lowered the costs and number of interviews as they were already presented with options they could choose from. The FGD lowered the costs in requirements gathering and efficiently gathered collective views on the UI. During the presentation of the prototypes and interview after that, the users checked whether their needs were met. They highly appreciated that they were consulted as to what should be in the device and be part of creating the software. They also took pride when the specified requirements were incorporated into the prototypes. It made them more interested in being involved and giving inputs knowing their feedback could be included in the output.

System Usability

System usability and user evaluation are essential steps before deploying technology on a wider scale. In this step, developers could infer how the users would behave with the proposed design in the actual situation i.e., issues, recurring errors, and additional requirements could already be documented for future interface improvements.[20] The repeated erroneous actions should hint the designers to develop design solutions to avoid these mistakes and ensure that the users perform the task correctly.[3]

Results of the SUS for the medium-fidelity prototype developed from this study point out that user find the interface usable and acceptable. With an SUS score of 81.94, it is beyond the threshold of 60 points and achieved a higher SUS score than reported by Custodio (68 points) in 2018[2]. This study's output is successful in improving the usability of the user interface design of HeLe device.

CONCLUSION

Developing a promising health technology requires a thorough analysis of the users' context, needs, and preferences for health ICT to be seamlessly and sustainably incorporated in care delivery. In the development cycle, the User-Centered Design approach actively involves end-users in each step, allowing them to bring suggestions and opinions on design and functionality. User acceptance has been one of the significant barriers to the deployment of health projects, mainly because relevant user preferences and usability issues have not been considered.

This study supports several prior research of Rothgangel et al. and Bath in demonstrating the worth of UCD in developing health ICT.[12,24] However, there is limited research in the Philippines that describes the end users' systematic involvement in the design of new technology, especially in health care. This study documents best practices and lessons learned in applying UCD methodology in design and development.

Different participatory methods and structured procedures (i.e., card sorting, MoSCoW matrix, CTA) were applied to help elicit and prioritize user requirements and feedback from the users.

The UCD methodology is undoubtedly time-consuming, but in the long run, can be cost-effective. It reduces major revisions or potential overhaul of the technology in the late stage. In essence, paper prototyping has been an efficient way to present and gather suggestions on designing the user interface. This could also be quickly revised on-ground, compared to an already developed device, to accommodate the demands and changes by the users. Digital mock-ups also require little to no coding and computer skills, and can be designed and redesigned faster than the actual product. The process was a crucial step that has resulted in a high degree of user acceptance of the Medium Fidelity Prototype among the target primary care health workers. Government research investments intended to democratize access to essential newborn hearing screening must successfully define what is user-friendly.

The most common considerations in user interface design are the presence of signifiers, constraints, feedback, and the organization of the information that should confirm what they are accustomed to. Users prefer that they understand what to do on a specific page at a glance (i.e. fonts, signifiers, instructions), be prevented from making errors (constraints and feedback), and can be alerted and allow to correct their mistakes (error-tolerance and education).

In general, the users believed that the design was easy to use and understand. They described the design as very user-friendly, simple, and straightforward to the desired action. The tabular format of the patient list, with emphasis on the pertinent information, was also preferred by the users as it enabled getting the patient details quickly. They again emphasized during the interview sessions that instructions helped them throughout the process, together with the visual prompts where the device can detect if they are doing the task wrong. The visual prompts also provided instructions on how to correct the wrong action which was very helpful according to them. Moreover, it was preferred that the instructions can be enabled or disabled depending on who is using the device. They believe that it was an important feature for the majority of the health workers who are not technologically adept, but would be a nuisance for those who are already accustomed with the technology.

Finally, they believe that the current design already allowed them to perform the intended function of testing the device. They also appreciated that the device follows the specific guidelines in testing newborn hearing screening. Most of the users are contented with the prototype of the UI and that there were no other crucial requirements that needs to be added.

This study documents practices and lessons learned in applying UCD methodology in design and development that have been demonstrated to improve usability of the UI design. The experience, tools, and lessons in the UCD methodology applied in HeLe prototypes can guide future research and eventually better understand ways to develop user-friendly telemedicine devices for the Philippines and also for other resource-limited environments. The reported findings and lessons learned might interest researchers, software, and hardware designers immediately. Health workers who will be at the user-end of innovations, program managers, chief executives, and policy makers can also consider these findings within their own spheres of influence, contributing to the future's desired innovative ICT-based health care system.

Recommendations

Due to resource constraints, the study's sample size is small and insufficient to illustrate the presence or absence of causal relationships on explored variables. It was limited to the application of UCD to HeLe interface. The Implementation Phase of the UCD methodology was not done. The usability testing is also limited to user feedback and does not provide sufficient insight to predict utilization or acceptance of the actual HeLe device. Nevertheless, this Medium Fidelity Prototype and other lessons from this UCD methodology are endorsed to the HeLe research team for use in the next stages of the investigational device development.

With enough budget and human resources, the research could be continued up to a high-fidelity or final prototype for testing. Future research could also assess the utilization and adoption of the device developed using this design methodology. A controlled trial could also be conducted to allow for a more direct comparison of the interface before and after the implementation of UCD methodologies.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

All authors declared no conflicts of interest.

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