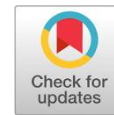




Revista Facultad de Ingeniería



Title: Technological development of a telemonitoring system (TELSY) for patients with heart failure



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DOI: **10.17533/udea.redin.20251188**

To appear in: *Revista Facultad de Ingeniería Universidad de Antioquia*

Received: April 23, 2025

Accepted: November 04, 2025

Available Online: November 04, 2025

This is the PDF version of an unedited article that has been peer-reviewed and accepted for publication. It is an early version, to our customers; however, the content is the same as the published article, but it does not have the final copy-editing, formatting, typesetting and other editing done by the publisher before the final published version. During this editing process, some errors might be discovered which could affect the content, besides all legal disclaimers that apply to this journal.

Please cite this article as: E. O. González, N. Peña-Novoa, S. M. Sanabria, J. S. Barrios, C. Matajira, P. Mejía-Maya, I. G. Aguirre-Arenas, J. M. de Hoyos and J. M. Martínez-Gómez . Technological development of a telemonitoring system (TELSY) for patients with heart failure, *Revista Facultad de Ingeniería Universidad de Antioquia*, Nov. 2025 [Online]. Available: <https://www.doi.org/10.17533/udea.redin.20251188>



Technological development of a telemonitoring system (TELSY) for patients with heart failure Desarrollo tecnológico de un sistema de telemonitoreo (TELSY) para pacientes con falla cardiaca

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KEYWORDS

Design thinking, Heart Failure, Patient monitoring, Telemedicine, Technological innovation, User-center design.

Pensamiento de diseño, falla cardiaca, monitoreo de pacientes, telemedicina, innovación tecnológica, diseño centrado en el usuario.

ABSTRACT: Heart failure (HF) is one of the leading causes of hospitalization in older adults, generating high burden on healthcare systems and negative impact in quality of life. Telemonitoring is a method that has shown effectiveness in reducing hospital readmissions and manage HF. Current systems face challenges related to usability, unfriendly interfaces, and unreliable data. To address these issues, Fundación Cardiovascular de Colombia developed TELSY based in design thinking methodology, a user-centered telemonitoring system. The aim of this article is to describe the technological development of the TELSY program, from its creation to its validation in laboratory environments. TELSY integrates three subsystems: TELSY Home, vital signs monitor that records biometric and self-reported data; TELSY Web, a platform for monitoring and clinical follow-up; and TELSY App, a mobile application that enables interaction between patients and healthcare professionals. Usability evaluations were conducted combining patient testing, healthcare professional assessments, and expert heuristic reviews. Results showed that while some tasks presented higher error incidence, overall satisfaction was high. TELSY App achieved strong acceptance and highly useful by participants. TELSY demonstrates potential as a scalable and sustainable solution to improve remote care and reduce hospitalizations in HF.



RESUMEN:

La insuficiencia cardíaca (IC) es una de las principales causas de hospitalización en adultos mayores, generando una alta carga sobre los sistemas de salud y un impacto negativo en la calidad de vida. El telemonitoreo ha demostrado ser una estrategia eficaz para reducir las rehospitalizaciones y manejar la IC; sin embargo, los sistemas actuales presentan limitaciones relacionadas con la usabilidad, interfaces poco amigables y datos poco confiables. Con el fin de superar estos retos, la Fundación Cardiovascular de Colombia desarrolló TELS Y, un sistema de telemonitoreo centrado en el usuario y basado en la metodología design thinking. El objetivo de este artículo es describir el desarrollo tecnológico del programa TELS Y, desde su creación hasta su validación en entornos de laboratorio. TELS Y integra tres subsistemas: TELS Y Home, un monitor de signos vitales que registra datos biométricos y autoinformados; TELS Y Web, una plataforma para el monitoreo y seguimiento clínico; y TELS Y App, una aplicación móvil que facilita la interacción entre pacientes y profesionales de la salud. Las evaluaciones de usabilidad incluyeron pruebas con pacientes, valoraciones de profesionales de la salud y revisiones heurísticas por expertos, evidenciando que, aunque algunas tareas presentaron una mayor incidencia de errores, la satisfacción general fue alta. La aplicación TELS Y App obtuvo una fuerte aceptación y fue considerada de gran utilidad por los participantes. En conjunto, TELS Y demuestra su potencial como una solución escalable y sostenible para optimizar el cuidado remoto y disminuir las hospitalizaciones en pacientes con IC.

1. Introduction

The care of chronic diseases in older adults is a public health challenge due to the high rate of hospitalizations and health costs [1]. The most frequent pathology in hospitalization services is heart failure [2]. Multiple telemonitoring systems have proven to be effective in reducing hospital readmissions; however, there are several challenges with the implementation of these technologies related to the lack of system usability [3], data reliability and integration of care models [4], which are necessary aspects for safe and effective monitoring. For several decades, information technology has been integrated into healthcare as an important resource, and today it is the result of three disciplines: computing, informatics and telecommunications [5]. That is why there is currently a large number of technologies applied to the field of health, some of them even articulated with IoT, which are oriented to monitoring, diagnosis and health care [6], and consist of solutions that can be integrated to internet infrastructure, applications and services that use them [7]. In other words, they allow ease of interaction, as a communication process between user and system through an interface [8].

Telemonitoring has proven to be a tool that facilitates the management of multiple pathologies, both acute and chronic, through the collection of physiological parameters (weight, heart rate, blood pressure, saturation, among others) which allow detecting any change in the patient's condition, with the objective of performing a therapeutic intervention based on management algorithms [5], [9] avoiding an admission to the emergency room and hospitalization stay; for consultation reasons that can easily be intervened on an outpatient basis or through a home accompaniment.



One of the pathologies that has benefited most from telemonitoring is heart failure, in which patients may present a decompensation of their disease and require emergency treatment and/or hospitalization. Telemonitoring is a promising strategy to avoid hospitalization for this condition [10]. In 2023 Scholte and collaborators [11] demonstrated through a systematic review and meta-analysis, the effectiveness of non-invasive telemonitoring in reducing the number of hospitalizations and all causes of mortality [11] in patients with heart failure. Given the early identification of signs and symptoms that can easily be intervened under other modalities of care or with the early intervention of health teams, which accompany the patient permanently.

Therefore, different telemonitoring systems are effective in the outpatient treatment of heart failure and the prevention of hospitalization for heart failure decompensation. However, some systems implemented in different countries [12], [13], [14], [15], [16] face a number of challenges regarding system usability and data reliability. Current systems lack usable and user-friendly interfaces for those with a low level of technological literacy [17], and in some studies biometric data are recorded manually, which increases the risk of errors in interpretation. In addition, some programs do not have verification and accompaniment in the care model by specialists, nor with intervention algorithms that ensure and standardize the process; likewise, there are systems that do not have an integrated electrocardiogram, which can limit monitoring and explore another series of complications. These technological barriers limit at times the possibility of effectively implementing telemonitoring schemes and the quality of information for clinical decision making and the possible risks of modifying treatments with unreliable data.

Taking into account that the maintenance of heart failure requires several self-care behaviors (adherence to pharmacological treatment, fluid restriction, low-sodium diet and physical activity) [18], telemonitoring should be a user-friendly technology that facilitates its adoption, health empowerment and better interaction with healthcare personnel [19], allowing data to be sent under criteria of reliability, security, centralization, traceability and structured data without causing an additional burden for patients and their caregivers.

Therefore, the Fundación Cardiovascular de Colombia has developed a telemonitoring system that allows the capture, transmission and visualization of biometric data of the patient, as well as a system that allows the identification of symptoms associated with heart failure by integrating different information and communication technologies. The aim of this article is to describe the technological development of the TELS Y telemonitoring program from its creation to its validation in laboratory environments.

2. Methodology

The development of the solution was based on a user-centered design methodology, particularly Design Thinking with iterative micro-cycles of analysis, synthesis and validation through its 5 main stages: Empathize, Define, Ideate, Prototype and Test (Figure 1). These design phases were grouped to facilitated understanding the problem to be solved with the necessary iterations to design the solution.

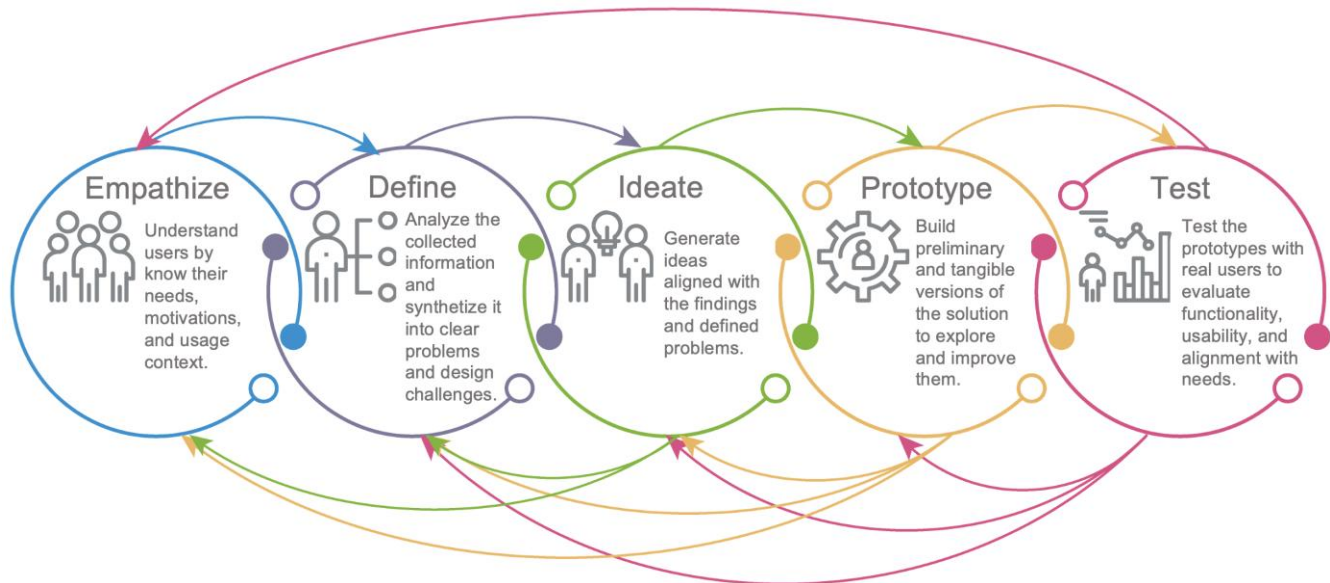


Figure 1. Phases of people-centered design. *Source: own elaboration.*

Empathize: First, 2 co-design sessions were held with the design and development team, made up of 4 employees and 3 interns, all from different areas of expertise, in order to understand what we knew about the problem, analyze the design challenge and define the different actors involved in the project through brainstorming activities, creation of personas in the first session, and a cartoon activity in the second session.

Co-creation workshops were held with health professionals from the heart failure program of the Fundación Cardiovascular de Colombia (FCV) to gather their needs, in which about 14 health care professionals participated, as well as heart failure patients, which were addressed with surveys of open-ended questions in which 30 people participated, including patients and companions. In this workshop, we applied the *person method* based on demographic profiles and the characteristics of patients with heart failure. Defining these profiles was essential, as they served as a reference throughout the different phases of the project.

Definition: In this phase, we identified the problem as the development of a telemedicine system comprising three subsystems: a home vital signs monitor, a telecenter for professionals in the heart failure program, and a mobile application for patients and their families. Based on the analysis of findings from the emphasis phase, the basic user needs were defined, and the project hypotheses were formulated.

Analyze: An in-depth investigation was conducted to identify user needs, behaviors, and expectations. The collected information was categorized using an affinity and relative importance diagram, which was then translated into design requirements. Semi-structured interviews, combined with brainstorming sessions involving 13 expert cardiologists, played a crucial role in enriching the TELS Y system's information repository.

Design: The initial concepts of TELSYPHogar, TELSYPweb and TELSYPAPP were defined by means of individual ideation tools such as Black Box Monitor and User Flows, where the graphic interfaces were created, the necessary parameters to be captured by the home assistant were identified, and the pharmacological adherence and lifestyle modules were defined. Additionally, the documentation for the usability tests was prepared, including moderation scripts, face-to-face and remote protocols and informed consents.

Finally, the concepts were evaluated through co-ideation sessions with the work team, during which the attributes and feasibility of the concepts were verified. Real users were invited to interact with the designs and provide direct feedback. Based on this input, the interface was defined and refined over three sessions, iterating on the design in each one until an intuitive, polished, and effective user experience was achieved.

Prototyping: Low-fidelity prototypes of the vital signs monitor, telecenter, and app were developed based on sketches and user flow diagrams. These were designed to facilitate interaction with various stakeholders, such as nurses and physicians in the heart failure program of Instituto Cardiovascular (ICV), to evaluate compliance with requirements, gather feedback, analyze new findings, and design actionable solutions. Notably, the development of the vital signs monitor started with a pre-existing patient transport device (Singcare). Research and characterization efforts were conducted to define the appropriate hardware to meet all design requirements established by the proposed methodology. Various electronic boards for vital parameter acquisition were evaluated, and experts were consulted to identify the best processing system for implementing a solution tailored to the identified needs.

Test: We used several usability evaluations; these were conducted following international standards (ISO IEC 62366-1:2015 and ISO 9241-11) where it combines user testing and expert heuristic analysis, these assessments involved patients (n=37) and health care professionals (n=21). For TELSYP Home, subjects had to performed predefined tasks (e.g., Wi-Fi connection, login, medication registration), to measure efficiency, effectiveness and satisfaction through eye-tracking, self-report surveys, and performance metrics. For TELSYP Web, usability testing with healthcare staff was carried out by task analysis, error tracking, and the Single Ease Question (SEQ) tool to evaluate ease of task completion. Expert reviews were carried out by specialists in design, ergonomics and UX, applying Nielsen's heuristics [20], and WCAG 2.1 accessibility criteria to all components. For TELSYP App, the research team had to evaluate different prototypes to choose the best option for the development, therefore the usability assessment was based on three key parameters: effectiveness, measured by the number of errors made during tasks; efficiency, reflected in the time required to complete each activity; and satisfaction, capturing the overall user experience and perception of the system. To add, perceived utility of TELSYP App was assessed using a unidimensional Likert-type scale ranging from 1 to 10, where 1 represented "not useful at all" and 10 represented "very useful".

Once the prototype of the home assistant (TELSY Hogar), monitoring telecenter (TELSY web) and the application (TELSYApp) were developed, they were tested in a controlled environment with 3 developers and a vital signs simulator. The test consisted of monitoring 3 times a day for 3 consecutive days. The start of the trial began with training to identify the key points and the effectiveness of the trial. The monitoring consisted of the participants taking physiological parameters (blood pressure, heart rate, pulse oximetry), as well as entering their weight and reporting symptoms, at the same time as the monitoring was carried out by an assisting staff. Errors made, alarms reported, and perceptions of the training were recorded, as well as establishing the monitoring protocol.

3. Results

The telemonitoring system called TELS Y was developed through a user - centered method, leading three integrated components for patients with heart failure:

TELS Y Hogar

A home assistant was developed based on vital signs monitor already implemented in the institution. The new development allows the capture of the following parameters: blood pressure, saturation, heart rate, respiratory rate and electrocardiogram; it is also possible to manually record weight, associated symptomatology through guiding questions, medication and physical activity, as well as to incorporate an education and self-care module (Figure 2).

The usability assessment identified some task that requires higher cognitive demand and error incidence, like wi-Fi connection, credential login, medication registration and weight entry. Despite these challenges, patients reported high satisfaction, emphasizing the device's utility for remote monitoring and clinical follow-up.



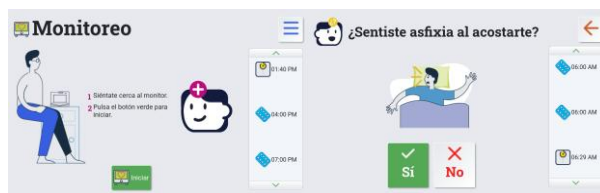


Figure 2. TELS Y Hogar. *Source: User interface of TELS Y home. The figure shows the home screen, options menu, daily goals, monitoring explanation, and an example of symptom self-report.*

TELS Y WEB:

A web page was developed to perform asynchronous patient monitoring. TELS Y web has a customized alerts module for each of the parameters taken and/or recorded in the home assistant. This web allows recording the daily analysis of the monitoring, as well as the assignment of parameters, medications and daily activities (Figure 3).

Healthcare professionals confirmed, through usability assessment that, TELS Y Web provides greater efficiency and clarity compared to conventional monitoring systems. However, tasks such as adding analyses and assigning daily goals presented a higher error incidence and increased monitoring time. Despite these challenges, overall satisfaction ratings were high. Participants emphasized the platform's potential to strengthen remote patient monitoring and enhance clinical follow-up in real-world practice.



Figure 3. TELS Y web. *Source: screenshot of platform. Screenshot of TELS Y web in the section for visualization EKG.*

TELS Y App:

As a result, we were able to develop an accessible and functional interface, aligned with the user experience and prioritizing shallow and simple navigation. The proposed alternative was highly rated, with 86.7% of users indicating that they would download and use TELS YAPP (Figure 4). In addition, the usability assessment revealed that TELS Y App was perceived as highly useful, with 63.6% of participants rating it at the maximum score of usefulness.



Figure 4. TELS Y App. *Source: Screenshots of TELS Y App, the figure illustrates the daily goals, weight recording, and symptom reporting*

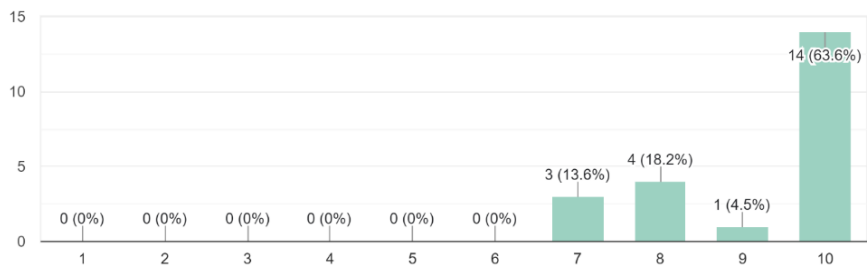


Figure 5. Utility scale. *Source: own elaboration.*

In-house testing:

Within the laboratory tests on healthy subjects, it became evident that training should be carried out in hierarchical order and instructions should be verified through verbalization of the actions by the participants to ensure understanding of the training. A total of 91 alerts were recorded, where 26% were minor, 21% medium and 53% critical (Figure 5). Adherence to monitoring was 100%.

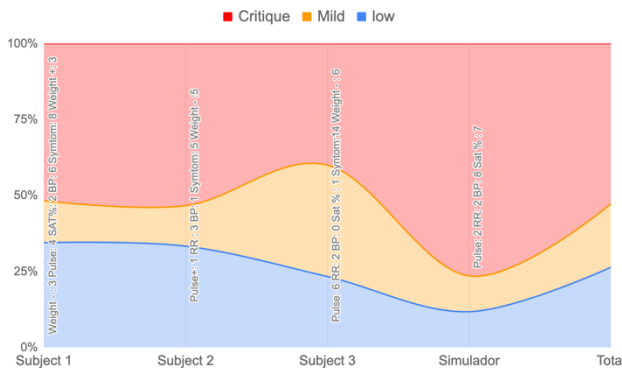


Figure 5. Alerts distributed per subject.

Data security implementation:



The system incorporates a security mechanism based on user passwords and role-based access control, ensuring that only users with the credentials can access specific functionalities. Authentication is handled through JSON Web Tokens (JWT). Each system (mobile app, web platform, and vital signs monitor) must perform login authentication by sending credentials to the API, which validates the request and generates a JWT. This token is stored locally within the client application and must be presented in every subsequent API request for data consultation and storage. For each transaction, the token travels in the request header using the Bearer authorization type. This architecture guarantees confidentiality, integrity, and secure communication across all TELS Y components.

4. Discussion

In the present study, a telemonitoring system called TELS Y was developed with 3 components: a home assistant (TELS Y hogar), telecenter (TELS Y web), and application (TELS Y app). TELS Y was designed and developed to face usability barriers, fragmented systems, and lack of data reliability. This system addresses these challenges by consolidating monitoring functions into a single system that ensures data integrity, promotes adherence, and facilitates communication between patients and healthcare professionals.

It is important to mention that one of the most noteworthy aspects is the user-centered design, where constant iterations were carried out to meet the needs of patients and health professionals. This process allowed us to create an interface aimed at being intuitive and adapted to the end user with the objective of ensuring the use of the system. This methodology has proven to improve the user experience allowing better clinical outcomes [21], in this case, focused on pharmacological adherence and follow-up to lifestyle recommendations.

It is expected that TELS Y can be used in the follow-up of chronic patients diagnosed with heart failure, COPD, Pulmonary Hypertension, and in acute patients, such as in the diagnosis of UTI (Urinary Tract Infections), post-surgery, among others, allowing early discharge from hospital institutions and that under strategies such as home care (hospital at home) a new scheme of extramural care can be generated where the clinical goals of improvement or maintenance of health can be achieved in a safe and relevant manner.

TELS Y provides an interface that allows intuitive and usable interaction. Additionally, the technological development of TELS Y was focused on maintaining data integrity by promoting data privacy and confidentiality. It is expected that this development can be implemented in the different models of care for chronic and acute pathologies.

Nevertheless, this study has some limitations that should be acknowledged. First, the usability tests were conducted in a controlled environment, which did not capture the real conditions that patients could experience; future evaluations should incorporate validated usability scales applied in real-world settings.



Second, the laboratory tests were not performed with patients diagnosed with heart failure, which limits the generalizability of the findings to this population. Consequently, clinical trials are required to evaluate the effectiveness and efficacy of TELS Y in reducing hospitalizations and mortality, as well as in improving quality of life among patients with heart failure and other chronic conditions.

Access to remote monitoring devices can transform healthcare by generating valuable data to better understand pathologies [22] and by improving follow-up in at-risk populations. However, technological development requires not only functional devices but also the integration of healthcare competences and organization infrastructure [23]. Those are key assets to ensure adoption, scalability, and sustainability of health technologies, particularly in emerging economies such as Colombia.

5. Conclusion

TELS Y is a user-centered solution that allows the transmission of physiological and health status data through a home assistant to a telemonitoring center to assess the condition of patients, take preventive actions and timely intervene in alerts generated, also allowing communication between care staff and patients through the App.

This system has the potential to reduce hospital admissions and mortality in chronic pathologies such as heart failure, being an innovative strategy to guarantee and improve access to health services.

In the medium term, there are plans to incorporate artificial intelligence algorithms to enhance prediction in the intervention with this type of systems, based on the data collected.

6. Declaration of competing interest

We declare that we have no significant competing interests including financial or non-financial, professional, or personal interests interfering with the full and objective presentation of the work described in this manuscript.

7. Acknowledgement

The researchers express their gratitude to the Ministry of Science, Technology, and Innovation (Minciencias) for the support provided for the implementation of the development presented within the call 818 – 2018

8. Funding

This work was supported in part by Ministry of Science, Technology, and Innovation of Colombia (Ministerio de Ciencia, Tecnología e Innovación – Minciencias) under the grant 818-2018 (n°project: 656680763306).

9. Author contributions



E. O. González, N. Peña-Novoa, S. M. Sanabria, J. S. Barrios, C. Matajira, P. Mejia-Maya, I. G. Aguirre-Arenas, J. M. de Hoyos: Study conception and Design

E. O. González, N. Peña-Novoa, J. S. Barrios, C. Matajira y J. M. de Hoyos: Collect the Data

Nicolas Peña Novoa, Edwin Orlando González, Paula Mejia Maya, Ivan Guillermo Aguirre Arenas: Draft

All the authors review and approved the final version of the manuscript.

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