Cardiovascular Disease Risk Predictor Using ISO 9241-210 and Artificial Intelligence Techniques: A Case Study

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Abstract. Currently, people suffer different diseases that degenerate their life quality. In Mexico, the number of deaths per year is commonly caused by cardiovascular diseases. Frequently, patients ignore having this condition until their health is complicated. For this reason, this article presents the design of a mobile application prototype of low fidelity, based on User-Centered Design. Using artificial intelligence techniques, data is collected to determine the patient's cardiovascular condition. In other words, the patient is classified early about the risk of cardiovascular disease. By joining UCD and ML. the first prototype of the cardiovascular disease risk predictor was found. The User-Centered Design (UCD) stages are implemented based on the ISO 9241-210: 2019 standard. The contribution of this work is the implementation of a simple and easy diagnostic tool. The evaluation and validation of the prototype was done through focus groups to carry out satisfaction and usability tests, obtaining satisfactory results.

Keywords: Cardiovascular disease, Mobile technology, User-Centered Design (UCD), Prototype, AI, K-Nearest Neighbors, Random Forest.

1 Introduction

Recently, according to the World Health Organization (WHO), degenerative diseases kill approximately 41 million people per year, accounting for 71% of global deaths [1]. Among the main degenerative diseases there are cardiovascular diseases. These diseases cause the death of 17.9 million people worldwide. In Mexico, in 2019, through reports from the Forensic Medical Services, Civil Registry and other institutions, a total of 747, 784 deaths were registered [2]. Where cardiovascular diseases occupy 23.5%, approximately 156,041 deaths. Based on the previous, an analysis is made in the development of prototypes for the prevention of cardiovascular diseases. Tools such as the Machine learning (ML), User-Centered Design (UCD) and mobile technologies create solutions to this type of problem. ML and UCD are used in the development of products and systems in healthcare [3], e.g., The use of UCD for diabetes detection. Where the UCD methodology was used to develop a mobile application for the care and prevention of diabetes in Mexico [4]. This research shows the different methodologies to be followed to develop user-centered products for health. All this based on UCD [5].

One way to enable the interaction between the human (user) and the ML is through mobile technology. There are mobile applications that function as a tool for patient healthcare. Such as administrative tasks like a medical consultations and services of the Mexican Institute of Social Security (IMSS) [6]. This type of advances in technology that involve mobile applications and UCD. can be useful in the work of healthcare experts and the Mexican healthcare system in general. Therefore, artificial intelligence is necessary for the development of supervised prediction algorithms focused on the health area. This allows the creation of user-centered tools (UCD) and also allows for competitive and simple technology in healthcare (ML) [7].

Machine learning (ML) analyzes different medical data and finds their correlation. This allows it to generate predictions about medical problems and scenarios. This reason it is important in the development of efficient and accessible medical care for patients [8]. By using artificial intelligence, people who are at risk of developing heart disease are studied and classified [9]. Currently there are many applications designed for people who seek to control and monitor factors related to heart disease, for example, blood pressure, heart rate, and others. These types of applications are created by programmers without the knowledge of a healthcare professional. As mentioned by David C. Klonoff, in mHealth for diabetes [11].

It is for this reason that there are different techniques that can be used for the design of a mobile application. But there is a specific methodology that is based on gathering and satisfying the needs of the target user, called User-Centered Design (UCD). It is a methodology created for designers to adapt their products to the needs of the target users and not the other way around. The objective of User-Centered Design is to understand the requirements of the target user. To succeed in developing useful, attractive and efficient systems for the users. In this way, to take advantage of the requirements provided and collected from the target user [12].

Derived from the mentioned above, this work develops the design of a prototype of a mobile application, which can be implemented in conjunction with an artificial intelligence technology. Using the methodology and stages of User-Centered Design (UCD), according to ISO 9241-210: 2019 [13]. This work provides a first approach to a tool for the prevention of cardiovascular disease risk. Through the processing of data obtained from users and taking the Risk Factor Questionnaire [14] as a reference. The user is provided with a quick and reliable prediction of the risk of cardiovascular disease. Recommendations for cardiovascular health care are suggested and an alert is sent to the physician or security contact in case of high risk or evident danger.

The main objective of the work is to provide a first prototype of a cardiovascular risk predictor that combines the advantages of DCU design and ML technology. A tool entirely focused on cardiovascular care. In addition, to open a breach in the design of applications focused on degenerative diseases that implement different technologies such as ML (this work) or add sensors and actuators (future work).

2 Related Works

It is known that different technologies have been implemented in the healthcare area, specifically talking about sensors and devices with UCD. For example, the stimulation of patients suffering from dementia [15], remote monitoring of patients with chronic diseases [16] and healthcare systems to support medical staff and confront the constant demand for medical services [17].

There are already different mobile applications based on UCD, that help users with their health care. However, in this paper, the purpose is not to compare them. It is to give an idea and context of what exists in the market, for example, application designed based on UCD for the care and treatment of diabetes. [4]. Another clear example is Everhealthier Women, a mobile health application, designed to provide women with an easy access to preventive health information [18]. There are also applications focused on cardiovascular disease care. Blood Pressure Watch, allows observing graphs related to the user's blood pressure statistics and sharing them with the healthcare professionals. In addition, it provides feedback to the user with reminders to record their blood pressure daily [19].

On the other hand, there is also a huge number of applications in other areas that collect specific user requirements [7]. All these applications have usability as a fundamental principle, and therefore, the target user as their main objective.

The prototype proposed in this work differs from the above, as it includes other specific characteristics focused entirely on the patient at risk of cardiovascular disease. Some of them are: age, sex, chest pain and others. The prototype allows feedback to the user with a clear prediction of suffering a cardiovascular disease. In the case of obtaining a high level of risk, immediately contact healthcare professional, as well as notifying a trusted contact. In addition, new features, such as serum cholesterol and glucose level, can be incorporated into the final design of the application. Finally, preliminary results of implementing machine learning algorithms such as Random Forest (RF) and K-Nearest Neighbors (KNN) are presented. This is to diagnose and prevent the development of cardiovascular diseases in an early and timely way. It is the first approximation of a prototype application that is designed based on UCD and ML technology, as a predictor of cardiovascular disease risk.

3 Materials and Methods

User-Centered Design (ISO 9241-210) is a process that involves the target users in the design and development stages of the prototype or product. This allows the prototype or product to meet the requirements of the target users. In this way, preventing complications and confusion when using the product. The International Organization for Standardization defined ISO 9241-210: 2019, to provide recommendations for design, based on different stages shown in Fig. 1.

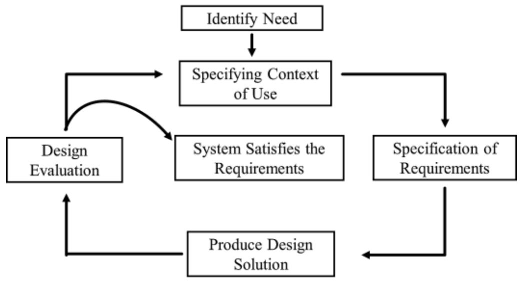

Fig. 1. User-Centered Design Stages - ISO 9241-210: 2019 [13].

UCD stages according to ISO 9241-210: 2019 [13]:

1. Specification Context of Use: This is the stage in which the target users of the system, the conditions and the application context will be identified. Implementing the "personas" technique.
2. Specification of Requirements: Identification of the target user's requirements and objectives, developing the system requirements based on the IEEE-830 standard.
3. Solution Production or Prototyping: Based on the data obtained in the previous stage, possible system designs and prototypes are produced.
4. Prototype Evaluation: In this stage the prototypes are evaluated to see if they satisfy the previous requirements.

Each of the stages observed in Fig. 1 are exemplified and developed below. For the development of the prototype application. The different stages are separated into the following subsections.

3.1 Stage 1: Specification Context of Use

The first step according to ISO 9241-210: 2019, is to identify the context and requirements of the target user. In addition, determine the feedback goals to be achieved with the development of the application. Potential target users were interviewed to identify their knowledge about health applications. In addition, using the "Personas" technique, a general profile of the target user was generated [20]. Thanks to this technique, the target user profile is between 30 and 65 years of age. People who are beginning to worry about their health. They commonly already use some type of application related to health, but not specifically to the heart.

Due to the current SARS-CoV-2 pandemic situation in the country, the questionnaires were carried out remotely. Digital tools such as Google Forms were used. Because it allows to create interviews for free, storing the information in graphs for later analysis [21].

3.2 Stage 2: Specification of Requirements

Based on the information obtained in the previous stage, the target user for the application is identified, as well as the age at which users begin to worry about their cardiovascular health. The different features, questions and aspects of the prototype application are based on the Risk Factor Questionnaire [14]. The main objective of this questionnaire is to identify people with different degenerative diseases. Basic information was collected for the development of the prototype.

3.3 Stage 3: Solution Production or Prototyping

This stage uses the information gathered in the previous two stages to generate a low-fidelity prototype, which means that the prototypes created do not contain a definitive appearance of the application. It serves to obtain information about the interaction of the target user and the application [22]. To achieve the development of the application prototype, Balsamiq Mockups 3[1] [23] was used. It is a low-fidelity interface design tool that uses wireframes. It allows creating code-free mockups, modifying and reorganizing graphical elements very easily.

3.4 Stage 4: Prototype Evaluation

After the previous stages were completed, the evaluation of the prototypes was carried out. The technique to achieve the evaluation is known as "focus groups" [24]. In addition, a questionnaire was implemented to evaluate the user experience, user preferences and personal opinion of the prototype [25]. To give functionality to the prototype, Justinmind[2] software was used [26]. This software allows to give functionality to the prototypes without the need to write code of any programming language. As a result, a working prototype was obtained and shown to a group of people. According to Jakob Nilsen, considered as one of the fathers of usability, he mentions that the number of users needed to perform the evaluation of a software is from 3 to 5. According to his study, the same results are obtained with a small group of users as with a bigger group [27]. That is why the same criterion is applied in this work. Evidently basing the questions and tasks on health-related information.

Machine Learning Algorithms

Machine learning consists of creating models that are able to perform specific tasks. Depending on the task, a machine learning algorithm can be chosen and adapted to classify or predict a result.

On the other hand, there are two types of algorithm groups: supervised and unsupervised. In this work, only supervised algorithms will be used. The group of supervised learning algorithms is characterized by learning from the inputs and

[1] Balsamiq Mockups 3, available: https://balsamiq.com/wireframes/desktop/docs/overview/

[2] Justinmind, available: https://www.justinmind.com/

outputs of the database. The database used in this work, was the "cardiac disease dataset" coming from the UCI Machine Learning Repository [28], the ddsm version. The objective of implementing ML algorithms is to introduce the information from this repository to the prototype that has been designed based on DCU.

This database has 14 features (for example: age, sex, etc.) and 303 instances (patients). Among the features used to create the cardiovascular risk classification model were: age, sex, chest pain, resting blood pressure, cholesterol, fasting blood sugar, maximum reached heart rate, exercise-induced angina, and finally condition, high risk (1) and low risk (0). First, a preprocessing stage was carried out. Different null values were detected and eliminated. Subsequently, attributes were introduced to develop two algorithms. All features were used. The Random Forest and K-Nearest Neighbors algorithms were developed. This is because they are one of the algorithms commonly used in the health area [29]. The development method was as follows: 75% for the training stage and 25% for the algorithm testing stage.

In order to validate the correct performance of the algorithms (how well they classify), it is necessary to perform an evaluation of the two algorithms. To evaluate performance, two parameters were considered: accuracy (Acc) and area under the curve (AUC). These parameters help to determine the ability of the algorithm to correctly classify patients at risk for cardiovascular disease or not. Accuracy can be calculated from the values of true positives (VP, patients with correctly classified risk), true negatives (VN, patients without correctly classified risk), false positives (FP, patients without incorrectly classified risk), false negatives (FN, patients with incorrectly classified risk). The accuracy value is between 0 and 1, i.e., the value close to 1 means a better performance for the correct classification of patients.

To justify this performance, the area under the curve is calculated from the sensitivity and specificity values. These represent the probability of the algorithm to correctly classify patients. The area is limited between the range of 0.5 and 1. Where if a value of 1 is obtained, it means that the algorithm perfectly classifies all patients. On the other hand, if a value of 0.5 is obtained, it means that the algorithm is unable to classify the patients correctly. In this way, a prototype application based on DCU and the implementation of artificial intelligence algorithms, were combined.

Finally, following each of the stages, a low-fidelity prototype was developed to classify whether a patient has a high or low risk of cardiovascular disease.

4 Results

From the implementation of the User-Centered Design (UCD) stages in the application prototype, the results of each stage are shown. In addition, the performance of the algorithms based on accuracy and area under the curve, is shown.

4.1 Specification Context of Use and Requirements

According to the questionnaire performed through Google Forms and the different questions asked, the opinions of 35 people were obtained. The number of persons interviewed was not higher due to the SARS-COV 2 contingency lived in the country.

The 35 persons interviewed accessed the interview through a mobile device. This situation made it very difficult to interact with the interviewees. An age range of 19 to 61 years was obtained. Fig. 2 shows the age ranges of the people interviewed. This figure shows that the largest number of respondents is in the 45 to 58 age range, with a total of 24 people, i.e., approximately 68%. This is possibly due to the evident concern of adults about the risk of suffering cardiovascular disease.

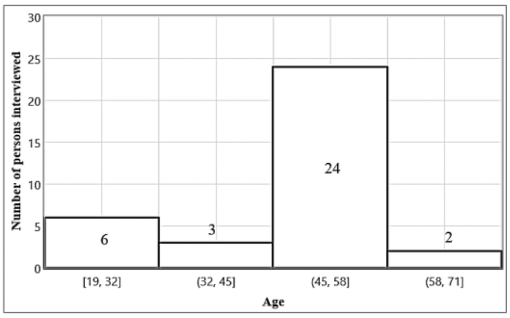

Fig. 2. Age of persons interviewed.

The main reason for users to use an application of this type is due to their interest in taking care of their cardiovascular health and improving their lifestyle. It is evident that a high percentage of those interviewed would have a cardiovascular problem. Most of them are over 45 years old. Cardiovascular diseases are more frequent in this age range, according to health experts. Based on the data obtained in the interviews, 66% of those interviewed said they already had a problem related to their cardiovascular health. This problem is shown in Fig. 3.

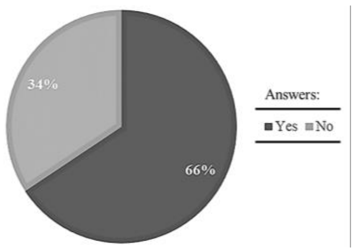

Fig. 3. Persons with cardiovascular problems.

Based in the Fig. 3, a question related to different aspects to be considered in the design of the application was included. This question is related to including an emergency button. Where 100% of the interviewees showed an interest in including a way to immediately contact a trusted contact or medical service. This button refers to having immediate access to send an alert with a single click. Avoiding searching in the phone book, the number of the trusted contact or medical service. Simply press a button and automatically send an alert that there is a problem.

Subsequently, a question was asked about how to provide feedback to the user. This refers to the way of displaying risk diagnosis of cardiovascular disease. Three different forms of feedback were proposed: by percentage, by risk ranges and by specific answer (Yes/No). 86.6% of respondents preferred to obtain concrete feedback. Preferred to receive feedback with: “Yes” or “No”. Fig. 4 shows the percentages for each way of displaying feedback.

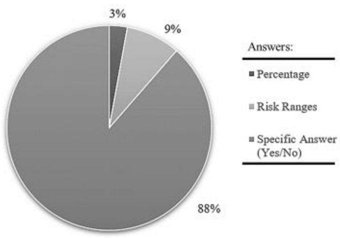

Fig. 4. The way of displaying risk diagnosis of cardiovascular disease.

Based on the data obtained from Specifications Context of Use stage. The requirements were compiled. This was obtained based on the IEEE-830 standard [29].

Then, the low-fidelity application prototype was created. This helped to design it in a simple way and in little time, this allows the evaluation and redesign. This prototype does not show a definitive version of the application; however, it will help to evaluate the functionality. The focus group method was implemented to support the user requirement specifications.

4.2 Solution Production or Prototyping

A first design prototype was made with basic elements. But evidently it needed to be redesigned. The colors in this first version were not very contrasting and it was deficient to have a registry of users. This allowed feedback from the users to improve the prototype. Two important aspects were emphasized: the registration of a user and the way in which data such as sex, age and chest pain were entered to perform the prediction. In addition, the colors were adapted and considered based on the recommendations. A new redesign was implemented.

In the second version of the prototype different modifications were made. Now the user can easily register. In this section, data to generate the output, such as age and gender, were recorded. This reduced the number of keystrokes (clicks on the screen) required to enter the information. This allows for easier interaction between the user and the prototype. In this new design an improved login was included. The new login design is shown in Fig. 5.

Fig. 5. a) Login Screen First version b) Login Screen Second version c) User Registration Screen Second version

In the first version, user registration screen was not available. In the second version a screen for user registration was implemented. This screen allows the user to enter data such as user name, age, gender, and others. At the end of the registration, the user is asked to enter directly to the parameter registration to start the classification diagnosis.

Subsequently, the interface where the type of chest pain suffered by the user is entered. In addition, the set of predictions previously made. A loading screen was added. Its purpose is to provide feedback to the user on the percentage complete of the diagnosis, as shown in Fig. 6.

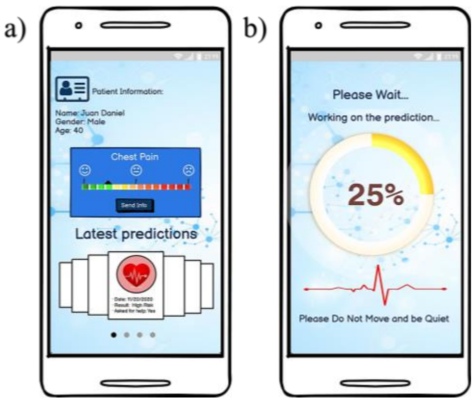

Fig. 6. a) Chest Pain screen with past diagnoses b) Load screen.

At the chest pain screen, all the user's information is displayed. To enter the user's chest pain level, just swipe the indicator. There are flags to help the user to decide the level of pain. Once the chest pain is entered, the user needs to press the "Send Info" button to start the diagnosis. Once the diagnosis is started, the loading screen appears. A percentage display allows the user to view the progress of the diagnostics.

Subsequently, an interface is displayed with the diagnosis corresponding to a high or low risk of suffering a cardiovascular disease. It is possible to observe that, in the case of high risk, an icon is displayed to send an alert message to the medical service. In addition, the user has the possibility to store or share the diagnosis through different options.

In this way, the user has the possibility to store or share the diagnosis through different options. For example, a screenshot or a .txt file. In the first case, the user could store as an image, the diagnostic obtained, with date and time. In the case of the .txt file, it would store each of the parameters obtained, as well as the patient's personal information to send by email or store it in the cloud.

On the other hand, the user can generate a new diagnosis or access the telephone menu to make a call. The diagnosis already generated will be automatically saved in the application so that it can be consulted later in the "Latest predictions" section.

Finally, some health recommendations for the users are shown. Each recommendation was proposed by cardiovascular health experts. This allows to offer a feedback focused on the diagnosis obtained, as shown in Fig. 7.

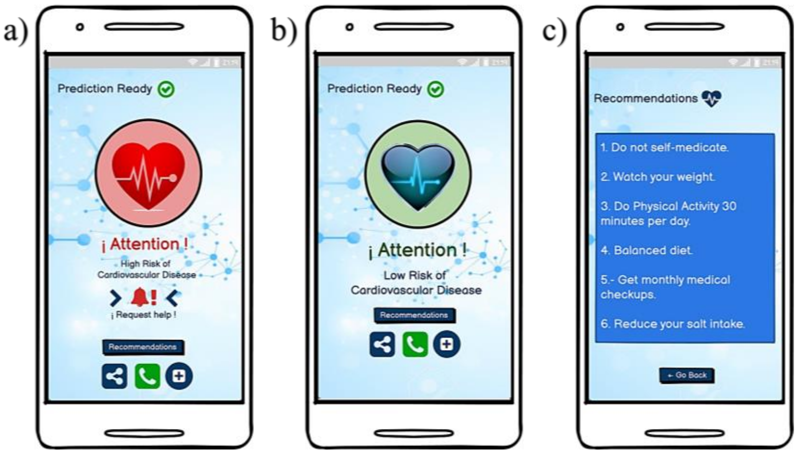

Fig. 7. a) High Risk screen b) Low Risk screen c) Recommendations.

4.3 Prototype Evaluation

From the second prototype previously generated, it was tested on 5 users. Each of them of different ages, physical condition and gender. This according to Jakob Nilsen [26]. It was explained to the users that it was a prototype and that the result obtained was not real, because no measurements or calculations were taken, as shown in Fig. 8.

Fig. 8. Prototype evaluation.

For the evaluation of the prototype, the focus group technique was used. The participants were adults between 49 and 60 years of age, who were subjected to simple usability tests. In addition, a series of questions were asked to evaluate their satisfaction. Users were instructed to perform 6 different tasks. This was in order to evaluate the usability over time of use. The name of the six tasks and the time that took to user number one were: User Registration (28s), Login (13s), Info Entry (8s), Diagnostic recognition (5s), Save diagnosis (12) and Start a new diagnosis (4s).

It can be seen that the user was able to correctly complete all tasks. The average time to complete a diagnosis is approximately 1 minute. The task that takes the longest time is the user registration. In other words, when using the application for the first time the user will have to spend a little more than one minute, but this time will be reduced later, because the user will not be required to register again. The same type of evaluation was performed on four other users. The data for the 5 users are summarized in Table 2.

Table 2. Performance of the 5 users and average time per task.

User	No. Tasks Completed	Average Time Per Task (Minutes)						Average Usage Time (Minutes)
		T1	T2	T3	T4	T5	T6	
1	6	28	13	8	5	12	4	12
2	6	25	11	9	4	13	6	11
3	6	28	12	7	6	16	9	13
4	6	26	11	7	6	15	8	12
5	6	26	14	8	5	12	10	13

From Table 2, it can be seen that the task that took users the longest time on average to perform was task 1. This task refers to user registration that ranges from 25 to 28 seconds. The task that took the least time for users to perform was task 4. This task refers to the recognition of the diagnosis. Users found the application intuitive and easy to interpret. After the task analysis, a series of questions were asked. These questions are designed to collect information about the user's experience according with [24]. The purpose is to get a feel for the user experience and to improve the prototype in the future.

1. How old are you?
2. On a scale of 1 to 5 (5 being the most difficult), how complicated is using the application?
3. On a scale of 1 to 5 (5 being the highest), how much do you agree that the application meets the objective?
4. What did you enjoy most about the application?
5. In general, what would you improve the application?

These questions were asked to the same 5 users. The following results were obtained: For question 1, the age range was between 49 and 60 years old, where 60% of the respondents are 54 years old. For question 2, the results were between 1 and 3, where 1 was easy and 5 was difficult. Users expressed that the application was intuitive and easy to operate. With respect to question 3, the results were 5 with 100%; the users stated that the prototype fulfilled the objective of predicting a patient with a high or low risk of cardiovascular disease, in addition to providing the necessary recommendations for taking care of their health. Users expressed a high interest in the application. They indicated that it will help to obtain an early diagnosis of cardiovascular problems. Users expressed a high interest in the application. They indicated that it will help to obtain an early diagnosis of cardiovascular problems. In addition, it is an accessible and quick guide to personal care. This helps to encourage taking expert recommendations. Regarding improvements to the prototype, users proposed the following: generate a more extensive history with other health-related aspects, e.g., alarms to take medication or the specific type of disease that may develop if care measures are not taken. In general, users demonstrated an ability to operate and navigate the application easily.

Finally, two machine learning algorithms were trained and tested.

4.4 Evaluation of Machine Learning Algorithms

Finally, two machine learning algorithms were trained and tested. The purpose of the development of these two algorithms was to compare which one classifies patients better. The classification was achieved thanks to the division of the 298 patients available in the database from the repository. Already as the null values removed in the preprocessing stage. 75% of patients were used for algorithm training. 25% to test. The main intention is to implement one of the two in the final version of the prototype. This will complement the development done during the user-centered design process. To evaluate the classification algorithms, the results obtained for ACC, AUC and some more details are show in the Fig. 9.

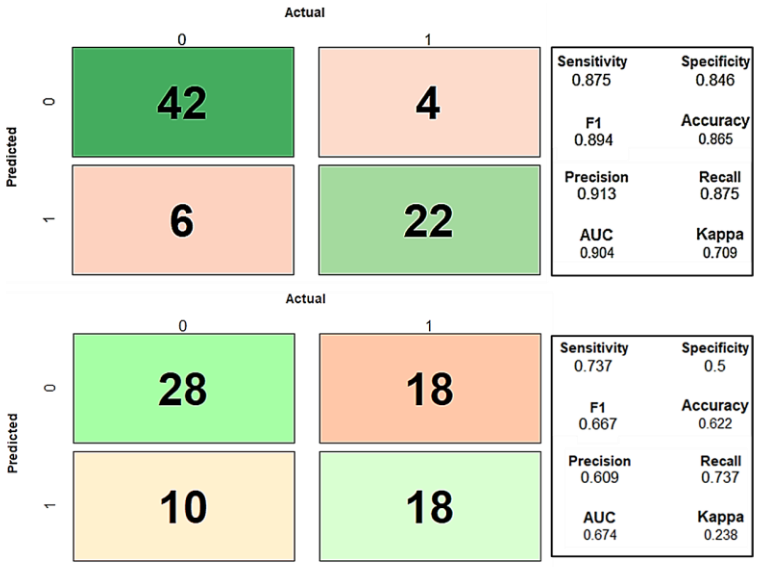

Fig. 9. Algorithm's evaluation.

From Fig. 9 it can be seen that the Random Forest algorithm classifies better (at the top). Of the 25% of patients used for testing this algorithm, 90% are correctly classified, according to the AUC obtained from the ROC curve. All this with an accuracy of 86% and precision of 91%. In simple terms, if the prototype application is used by 10 people, 9 of them will receive a correct diagnosis about the risk of cardiovascular disease. On the other hand, the KNN algorithm is shown to be more erroneous and to give an incorrect diagnosis (at the bottom). Therefore, it is discarded for implementation in a final version of the prototype. It is important to note that the prediction obtained in this section is a first result, it is clear that the algorithms can be improved and obtain better performance.

5 Discussions and Conclusions

Given that the questionnaire used for cardiovascular diseases and complications has been validated by the Mexican government, it was used as the basis for the creation of the prototype application. The database used in the study does not include demographic data from Mexico. On the other hand, it gives a clear idea that, if a database with patients from specific areas is obtained and used, the prototype works and adapts to the environment of use. Thanks to the User-Centered Design, it was possible to generate a first useful approximation of an application prototype that complies with the requirements and features of the target user. Based on the evaluation tests and the feedback obtained from the users, the prototype has good acceptance in functionality and design. In another words, the results obtained, allow the work to take into consideration the use of artificial intelligence and the use of electronic sensors. It is important to highlight that more studies and analysis are required to improve this tool. This work allows to open the gap to start developing applications or tools about specific health diseases. This in order to combat or detect early problems in patients. The future goal is to develop a complete tool, i. e., more information, features, software, testes and UX experiences. This will help to generate a simple and easy-to-use cardiovascular disease prevention tool. Finally, confront the problems related to deaths due to the health problems in Mexico. It is important to note that this work shows a way to unify UCD and technology as ML. In the future we will seek to integrate sensors and actuators capable of measuring different patient attributes. To finally open a breach of research related to health, DCU, ML and hardware.

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