Research Article

# A Conceptual Framework Architecture for AI-Based Remote Patient Monitoring in Diabetes (RPM-D): Gap Analysis and Feasibility Assessment

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## Abstract

Diabetes management is not only disease management but lifestyle modification with a strong vigil on diet, exercise, habits, regular consultation with doctors, pre-diagnosis, and monitoring of self-vital health parameters. Several AI-powered Diabetes diagnostic systems are out on the market. However, the efficiency of the entire AI-based Smart Healthcare Monitoring or Diagnostic Eco-System for Non-Communicable Diseases such as Diabetes depends on User Experience (UX), Quality by Design (QD) and Patient/Customer Centric Design thinking. This research paper studies the RPM architecture through intelligent wearables, the universal portability of the application, and various user-centric vital health parameters which are existing and new to be incorporated. The RPM Architecture for Diabetes (RPM-D) has been prepared to take the view on the gap analysis through initial qualitative interviews of physicians and their patients, then constructed questionnaires taking a combined literature review and the interview data and online/offline survey done for multiple stakeholders to find out a robust framework of model and its feasibility, validity and hypothesis tested through Structure Equation Modelling in Smart PLS 4. Finally, an architecture based on the basic requirements of RPM-D with more information on patients' needs is discussed.

**Keywords:** AI-based Diabetes Diagnosis adoption; UX in Smart wearables; Diabetes Product Management; QD in Smart wearables; Remote Patient Monitoring

## Introduction

Diabetes may be described as a sickness or condition where the body cannot adequately use the insulin generated. It is usually advantageous to identify Diabetes as soon as possible because it lowers the chance of diseases like heart illnesses, renal difficulties, eye disorders, brain strokes, etc. There are about three hundred forty-seven million diabetics worldwide (Five per cent of the world's population). Almost 80% of Diabetes reside in developing nations like India. Continuous robust monitoring of health vitals is required for patients who have Diabetes, as their blood sugar should always be regulated. Several studies on wearables/sensor-based Remote Patient Monitoring systems related to Diabetes are available but lack clinical decision-making about the patients. This is an essential parameter for developing countries like India, where there need to be more qualified medical personnel and health care facilities [1]. Technology advancements such as Artificial Intelligence (AI) have made it possible to accurately diagnose and predict these diseases. Whether using big data and Artificial Intelligence (AI) tools for scouting, planning, and monitoring or "personalized data" in common electronic record frameworks and tailored treatment standards, there may be centralized data for health system frameworks. The growth of digital health also brings issues, such as who owns and controls. It uses the collected data and how to maintain security and confidentiality in this information-rich environment.

On the other hand, the below-mentioned essential system requirement and development steps must be taken care of to construct any healthcare system, device or its program and application, such as identifying the exact requirements/related specifications, their design and development, then testing at every step of product development, and ultimately implementation [2,3]. The system architecture must be established before the system's design, and the system will then be built by that architecture [4,5]. The architecture is an abstract description of the information flow between and among the subsystems comprising the entire system [5,6].

There are 77 Mn Diabetics in India and counting a considerable dearth of technologically trained Doctors, caregivers, institutions and hospitals [7]. Diabetes management is not only disease management per se. It is about lifestyle modification with a strong vigil on diet, exercise, habits, regular consultation with doctors, pre-diagnosis, and monitoring self-vital health parameters. However, the different applications of Artificial Intelligence (AI) in Diabetes management are revolutionizing the healthcare industry by offering factual accuracy, productive efficiency, usability and satisfaction to doctors, their diabetic patients, beneficiaries and caregivers. Nevertheless, a single solution or application cannot fit all. There is an urgent need for a customized patient-centric approach for individual cases. When a systematic analysis of recent medical literature from PubMed and other similar sources was conducted it is found that AI has transformed Diabetes management through 4 broad, diverse and complex ways, for example, clinical decision support



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system, patient self-management/monitoring tools, automated retinal screening and demographic risk stratification. Many AI-powered decision-support tools are currently available on the market, with more on the horizon, including retinal imaging apparatus, predictive modelling software, glucose monitors, insulin pump machines, smartphone apps, and varieties of tools. Due to the widespread use of smartwatches, smart wearables, AI-based sensors as well as Remote Patient Monitoring (RPM) systems, it is anticipated that the use of artificial intelligence in detecting Diabetes will grow tremendously in the coming days. However, knowledge and inclusion of User Experience (UX) with Quality by Design (QD), and Patient/Customer/Consumer-Centric Design thinking during AI-based Diabetes diagnostic intervention system development are the need of the hour to manage the expected outcome of the products and their Eco-system to detect Non-Communicable Diseases like Diabetes. By enabling researchers to look into the technical, social, and cultural components and comprehend the relationship between those factors and users' preparedness to utilize healthcare systems, identifying these factors will increase the effectiveness of healthcare technology. As a result, the objective of this study is to empirically assess how various stakeholders have adopted or will adopt AI-based Diabetes Diagnostic Systems. Stemming from this aim, we intend to answer the following research questions:

RQ[1]. Is there any correlation/s existing between User Experience (UX) with Quality by Design (QD) and Patient Centric Design Thinking (PCD) towards Usability (U) of AI-based Diabetes Diagnostic Interventions as per the perception by different stakeholders?

RQ[2]. How can these variables be integrated to develop a robust framework model for measuring the application adoption by different stakeholders and testing the feasibility?

RQ[3]. What are different aspects of existing vital health parameters and more to be incorporated with recommending an architecture for Remote Patient Monitoring for Diabetes depending on the above framework?

To evaluate the AI-based diagnostic intervention in the Indian healthcare system and provide protection and information trustworthiness while addressing issues with social acknowledgement, consent, risk, and clarify capacity, there is an urgent need for a sustainable framework and feasibility assessment. Along with doctors, medical assistants, and analysts, AI-powered specialists can look for, find, introduce, and apply the most recent clinical and medical information, enhancing clinician productivity, limit, and type of care.

A recent study compares traditional clinic-based glucose monitoring with continuous glucose monitoring systems to weigh the benefits and drawbacks of each in terms of acceptance, appropriateness, and usage [8].

El-Gayar examine Apple App Store-accessible commercial applications from January 1995 to August 2012 [9]. The recommended apps are self-management chores to control diabetes and manage life thereafter. According to the assessment, there should be advancements in usability, patient-electronic health record integration, and individualized feedback. Several non-invasive glucose monitoring methods are currently available, according to Vashist [10]. These consist of approaches based on light, sound, and electrodes. The review examines some commercially available glucose monitoring devices and outlines the benefits and drawbacks of each of these approaches. These devices must improve accuracy, precision, cost, and reaction speed. A study of previous works on diabetic self-management mobile applications is presented in a recent review [11]. Szydlo and Koneiczny have discussed contact-based solutions for Diabetes with EEG and glucose monitoring [12]. The remote monitoring approach by Kozlovszky et al., uses ready-to-wear sensors to detect Diabetes [13]. A qualitative study was done by Rasmussen et al., on applications of remote monitoring systems for diabetic foot ulcer patients [14]. The diabetes management system has an automatic feedback message generation feature that can record food consumption, blood pressure measurement, blood glucose level, weight, drug intake, and physical activity [15]. Additionally, it contains a message repository with messages shared with the patients as needed, as well as doctor and patient chat functionality. A technique for tracking diabetic patients is offered by Suh et al., and has been approved by the Weight and Activity with Blood Pressure and Other Vital Signs (WANDA) mostly a project for heart failure patients [16].

The research by O'Grady et al., on a mobile glucose monitoring and control device used two specific systems such as a Medtronic Paradigm Veo insulin pump connected to a Portable Glucose Control System (PGCS) that interacts with the BlackBerry Storm smartphone platform and a Bluetooth radio frequency translator [16]. When a proper communication is established between the sensors and the insulin pump, the patient is administered the required amount of insulin. The system is mainly useful for type 1 Diabetes patients and it also uses a venous plasma glucose monitoring sensor separately; whenever the level of glucose rises in two successive measures it triggers an insulin supplement. These two are mainly independent studies on patients where the closed-loop operation and feedback mechanism of the first system have produced better results with blood glucose maintenance (over the duration of more extended periods) compared to the open-loop approach. Ly et al., described a comparable closed-loop system where Mobile devices (such as Sony Ericsson or Xperia) and other sensors (like the Dexcom G4 Platinum glucose sensor) were used [17]. A web-based tool was used to transfer the data to a PC so medical professionals could monitor remotely. A contactless method to diagnose diabetic retinopathy was explored by Askew et al., where patients received treatment in a primary care setting while occasionally having their retinas photographed [18]. Tele-ophthalmologist consultations *via* teleconferencing are used to provide ongoing care. In a recent study, the practicality of using photographic foot imaging technology to monitor diabetic foot ulcers was assessed. After that, the patient's Health-Related Quality of Life (HRQoL) was assessed and improved [19].

A mobile health system has been proposed by M. Chen et al., to continuously assess and monitor diabetes patients using 5G [20]. In order to provide complete monitoring and analysis for diabetes patients, researchers in this study first offer the wearable 5G-Smart Diabetes system, integrating machine learning, and big data with already-available technology.

Data-sharing and data analysis paradigm of diabetes through 5G is demonstrated by the researchers in this study. Finally, the researchers developed a 5G-Smart test environment for Diabetes. The results show how well the system can provide customized diagnoses and therapies [21].

## Material and Methods

In 2020, Goyal et al., proposed an intelligent home health monitoring system for forecasting type 2 diabetes and hypertension [22]. The system aims to assess the patient's blood pressure and glucose readings taken at home. The carer is alerted if an anomaly is discovered. A supervised machine-learning classification technique is used by the system to detect the existence of Diabetes and hypertension [23].

A novel method to predict glucose concentration for diabetic individuals was proposed by Ahmed et al., In this study, the researchers used the GlucoSim programme to analyze patient data [24]. There is a certain requirement for Continuous Glucose Monitoring Sensors (CGS) and the Kalman Filter (KF) used in this system to decrease noise. This method helps shield against serious hypo or hyperglycemia-related issues.

K. Kannadasan et al., have provided a classification of the particular datasets for Pima Indian diabetes patients with higher accuracy and many more evaluation measures [25]. For identifying diabetes data, the authors propose stacked autoencoder usage in a deep neural network framework. The precision of the system including recall and specificity also the F1 scores are employed in the tests as evaluation metrics. An ensemble learning algorithm named XGBoost is introduced by L. Wang et al., to forecast the likelihood of getting type 2 diabetes, enhancing the predictive value of existing models [26]. Support Vector Machines (SVMs), Random Forests (RF), and K-Nearest Neighbours (KNN) are all put up against each other in this study. A. Chardonnay et al., propose employing machine learning methods such as K-Nearest Neighbours (KNN), Logistic Regression (LR), Support Vector Machines (SVM), and decision tree classifiers to predict CKD using clinical data [27]. A performance comparison of several models has been carried out to establish the most effective technique to predict chronic renal illness. A model to categorize certain heart conditions is provided by H. Yoo et al., which has a quick and effective pre-processing method and a deep neural network to analyze the real-time accumulated biosensor input data [28]. S. González-Valenzuela et al., offer a healthcare monitoring system based on a handoff mechanism for ongoing home monitoring of ambulatory patients [29]. In the two-tier network architecture of this system, the access point and the body sensor network coordinator device are connected point-to-point. Vital signs are gathered using one layer of wearable sensors (AP). The results of the tests indicate that it is possible to lower the packet loss rate to 20% of the value that would otherwise be obtained just by utilizing the coordinator-AP link. The patient's wrist was where the sensor was worn, and when they walked at 0.5 metres per second, the results were the most significant.

Finally, we review various works with machine-learning techniques at their core. Izonin offers two specific methods required for handling the classification problem of medical implant materials, which are based on compatibility with Wiener polynomials and SVMs [30]. The author compares the proposed techniques to existing algorithms.

Clinical Decision Support Systems (CDSS) Architecture in Korea is an article that discusses CDSS architecture with Electronic Health Records (EHR) [31-33]. It was suggested that the CDS service be connected with Hospital Information Systems (HIS), given that the CDS architecture offered is an autonomous service [34]. Because they see the knowledge engine as a critical element of establishing knowledge services, they advocated interoperability between CDSS and knowledge engine architecture. A hypertension guidelines application was developed to test the CDSS architecture and knowledge engine. Using domain experts' knowledge bases, medical databases, and the most recent academic studies, El-Sappagh and El-Masri created a novel CDSS architecture that uses data mining techniques to generate cooperative knowledge bases [35]. The data mining engine is linked to the clinical and EHR databases, and it continuously mines extremely current knowledge to expand the local knowledge base. Other institutions' specialized knowledge sources can also be consulted for pertinent information. According to El-Sappagh and El-Masri, this architecture will connect scattered EHR systems from different institutions to scattered information sources for certain diseases [36]. Khalid et al., offer a case study of a cost-effective healthcare system for patients in rural Pakistan [37]. The system's architecture comprises the wearable medical sensor module, data collecting module, Personal Digital Assistant (PDA), remote server with CDSS and Electronic Medical Record (EMR) capabilities, and web-enabled remote terminal for accessing web server services. The EMR will then record the data against the patient profile when the remote server contacts CDSS for data analysis. Feedback is sent to the doctor for approval prior to being transmitted to the PDA after CDSS processing of the data. The CDSS software examines the patient's physiological data, including the ECG, blood pressure, temperature, etc., for potential anomalies. Depending on the data it has received, the software may project the health state and make decisions depending on the current state of the user's health. The privacy and security of the medical information transferred by Remote Patient Monitoring (RPM) systems represent a substantial hurdle to their widespread use. Since the RPM system will transmit the patient's confidential medical information over the network, including Local Area Network (LAN) and Wide Area Network (WAN), any conceivable RPM system design must consider privacy and security concerns. While patient information is private, shady employers, dishonest insurance companies, malicious hackers, and the media could still get unauthorized access. We can determine that data security is an essential component of the RPM system after looking at recent examples from Dr Lal Pathlabs and AIIMS, Delhi. The regulations governing the privacy of patient data must be adhered to by the RPM system. The ability of the RPM system to protect patient data privacy and confidentiality will determine whether or not it is accepted [38-41].

This research paper studies the Remote Patient Monitoring for Diabetes (RPM-D) architecture through smart wearables, universal portability of the application, and various user-centric vital health parameters to be detected, including a comparison of existing and later to be incorporated. Also, this research detail the novelty of the method compared to digital ethnography and how to use the method considering ethical concerns such as user privacy, user consent etc. The basic requirements of the RPM architecture, evaluation and value addition of this research contribute to design science. There are qualitative interviews of General Physicians, Diabetologists, and MD and DM Physicians and their Patients conducted to understand the gap and opportunities with online/offline surveys amongst doctors and different users of the AI-based Diabetes diagnosis system, smart wearables/applications to estimate the significance of UX, QD, Patient centricity, Ethical consideration to innovate new product/platform development for successful multiple stakeholder usage.

## Data collection

**Qualitative interviews of physicians and their patients:** Physicians were approached to take part in this study in December 2022 by direct walk-ins at hospitals and diabetes clinics located throughout Bangalore. The main requirement for this interview is to find doctors willing to talk about how they treat diabetic patients and who might propose one of their patients for an interview as well. A consent form and project information were emailed to the first 15 responding doctors, and they all agreed and participated in the study. They were then instructed to choose a patient who was receiving treatment for Diabetes and who could be a good candidate for an interview. After that, the patients were called and asked to participate in the study. We contacted 15 patients, and all but one consented to the study. The doctor found a replacement for a patient who needed to be more eager to participate. All interviews were performed over the phone by the same interviewer. Each participant voluntarily agreed to be interviewed in writing. A semi-structured interview guide was used for open-ended interviews. Not all doctors and patients were questioned in full. Instead, because this study was exploratory, we were particularly interested in the unprompted comments made by the doctors and patients. Each interview lasted between 25 and 45 minutes, was taped, and was then written down.

Interviews with doctors focused on how they identified and treated people with Diabetes. They covered topics like the adoption of the AI-based diabetes diagnosis system application and its various characteristics. We wish to focus on patient awareness, eating habits, self-monitoring vital metrics, remote patient monitoring, and overall, and even more, if you would like, your involvement in caring for your patients with Diabetes. Please respond to the questions in general and then specifically as they apply to your patient who has also consented to be interviewed. The focus of patient interviews was on the role that AI-based diabetes diagnostic systems play in self-monitoring patients' health vitals for diabetic management and new parameters that need to be added. The Institutional Review Board (IRB) of the Institute of Health Management Research, Bangalore (IIHMR-B), approved the study procedure. We modified a technique Miles and Huberman used to standardize and present interview data [42]. The features of the doctors we spoke with, statements made during free-form discussions, and traits of their patients are all summarised in Table 1-3, Annexure I.

**Table 1: Outer loadings – Matrix through Smart PLS 4.**

| | EC | PCD | QD | U | UX |
|---|---|---|---|---|---|
| EC | 1.000 | | | | |
| PCD1 | | 0.911 | | | |
| PCD2 | | 0.934 | | | |
| QD1 | | | 0.931 | | |
| QD2 | | | 0.870 | | |
| U1 | | | | 0.654 | |
| U2 | | | | 0.869 | |
| U3 | | | | 0.907 | |
| U4 | | | | 0.833 | |
| U5 | | | | 0.781 | |
| UX1 | | | | | 0.461 |
| UX2 | | | | | 0.242 |
| UX3 | | | | | 0.972 |

**Table 2: Construct reliability and validity through Smart PLS 4.**

| | Cronbach's alpha | Composite reliability (rho_a) | Composite reliability (rho_c) | Average variance extracted (AVE) |
|---|---|---|---|---|
| PCD | 0.826 | 0.838 | 0.920 | 0.851 |
| QD | 0.773 | 0.820 | 0.896 | 0.812 |
| U | 0.868 | 0.875 | 0.906 | 0.662 |
| UX | 0.516 | 1.072 | 0.611 | 0.405 |

**Table 3: Discriminant validity Heterotrait-Monotrait Ratio (HTMT) through Smart PLS 4.**

| | EC | PCD | QD | U | UX |
|---|---|---|---|---|---|
| EC | | | | | |
| PCD | 0.764 | | | | |
| QD | 0.862 | 0.836 | | | |
| U | 0.568 | 0.594 | 0.591 | | |
| UX | 0.313 | 0.402 | 0.397 | 0.720 | |

## Online/offline survey of physicians, patients, caregivers and beneficiaries

To find and evaluate a robust framework architecture for AI-based Diabetes diagnostic system application adoption among different stakeholders, we have conducted an online/offline survey with questionnaires mostly adopted from the statements/issues that came out during open-ended discussions with them mentioned in Table 4, Annexure I and a few more added from available academic and industrial pieces of literature. We, at this moment, conducted an exploratory study of multiple stakeholders' adoption parameters for AI-based Diabetes diagnostic intervention; this research aims to create a proposed Model of Usability for RPM-D (MURPM-D) and test the validity and reliability of the model through structural equation modelling. Physicians, patients, caregivers and beneficiaries who used an AI-based diabetes diagnostic intervention or directly or indirectly experienced it made up the research group. Totally 100 responses were collected through online/offline surveys. A five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) was used for objects containing the questionnaire constructs and other features. Respondents were asked to provide input on AI-based diabetes diagnosis intervention, its direct or indirect experiences, different health monitoring parameters and qualities to be incorporated in the design, ethical considerations etc., impacting the system's usability. The questionnaire and model construct with the measurement scale are shown in Annexure II. To check the quality and efficiency of the calculation model, the data were evaluated using the Smart PLS version 4 and Structure Equation Modelling (SEM). Later conceptual RPM-D architecture is proposed considering all the factors impacting usability.

**Table 4: Discriminant validity Fornell-Larcker criterion through Smart PLS 4.**

| | EC | PCD | QD | U | UX |
|---|---|---|---|---|---|
| EC | 1.000 | | | | |
| PCD | 0.700 | 0.923 | | | |
| QD | 0.770 | 0.676 | 0.901 | | |
| U | 0.533 | 0.507 | 0.499 | 0.814 | |
| UX | 0.430 | 0.368 | 0.392 | 0.678 | 0.636 |

## Development of theory and proposed hypotheses

According to Nathan in the chapter 'Design-thinking approach to ethical (responsible) innovation' in the book "Responsible Research and Innovation", the technological design-thinking method, particularly in the context of emerging and convergent technologies, may promote ethical (responsible) technical innovation even though it presents many implementation difficulties, because of its emphasis on human-centred design and other fundamental qualities like empathy. Emerging technologies such as autonomous vehicles, drones, and next-generation robotics may present ethical problems ingrained at the machine level, necessitating knowledge of machine-level ethical concerns and considerations [40]. The nascent new discipline of "machine ethics" has progressively addressed these issues. Therefore, it is crucial to incorporate ethical decision-making into both the organizational-level and machine-level innovation processes. So, we propose the first hypothesis as follows:

**Ethical Considerations (EC) significantly positively impact Patient-Centric Design Thinking (PCD):**

Papagni et al., stated that artificial agents are gradually becoming more prevalent in daily life and developing increasingly advanced interaction affordances [43]. In some particular situations, such as Google Duplex, GPT-3 bots, or Deep Mind's AlphaGo Zero, their abilities are on par with or better than those of humans. It is necessary to make such agents understandable to laypeople due to the user settings of daily life. The controversy over adopting Dennett's "intentional stance" has also been sparked by the demonstration of human levels of social conduct. They also argue that it is possible to attribute intentions to an agent's activities if they are open about their design principles and functionality. In this context, we propose our next hypothesis as follows:

**Ethical Consideration (EC) significantly impacts Quality by Design (QD):** Roma et al., mentioned that usability engineering methodologies and user participation during medical device creation might help prevent significant adverse events caused by user errors [44]. Application of current technological usability standards, use of health technology evaluation literature, and consideration of ethics-related particularities of medical device design should be the pillars on which it is founded. Henceforth we propose the following hypothesis:

**Ethical Consideration (EC) has a significantly positive impact on Usability (U):** Altman et al., stated that if design thinking is applied to health care, that could improve creativity, superior efficiency, and somehow effectiveness by emphasizing patient and provider requirements [45]. Although its application varies, design thinking is employed in various healthcare environments and situations. Notwithstanding methodological and quality restrictions, design thinking may produce useable, acceptable, and effective treatments. So, we propose our next hypothesis as follows:

**Patient-Centric Design thinking (PCD) has a significantly positive impact on Usability (U):** Kandaswamy et al., stated that Clinical Decision Support (CDS) is a method for incorporating applicable, organized clinical knowledge and patient information into choices and activities related to health that can dramatically enhance patient outcomes and healthcare delivery [46]. Their influence on clinical results, however, has fluctuated. It is vital to conduct rigorous and ongoing evaluations of CDS to improve CDS. The team has built an interface prototype using assessed User and Task analysis for usability and efficacy in determining how well CDS performs to enhance quality outcomes. The findings indicate that assessing CDS effectiveness is challenging and that additional study may be required to help users get the correct conclusions. So, we may propose:

**Quality by Design (QD) has a significantly positive impact on Usability (U):** Fronemann et al., stated that it is essential that the users accept social robots to integrate them into real-world settings. Acceptance is heavily influenced by the user's perception of the interaction and the robot's capability [47]. To design robot behaviour for the comfort and well-being of the user, established design ideas from usability and user experience research can be used in human-robot interaction. However, concentrating the design solely on these factors has specific moral difficulties, particularly regarding the user's autonomy and privacy. They also suggested modifications to the original design concepts and proposed their design for a positive and morally sound social human-robot interaction design. They demonstrated that while ethical design and good user experience may occasionally conflict, they may frequently coexist, provided designers are willing to modify tried-and-true design principles. So at this moment, we come up with our next hypothesis as follows:

**User Experience (UX) has a significantly positive impact on Ethical Consideration (EC):** Despite the general optimism about its possibilities, Duffy et al., stated that efficacy, adoption, usability, and patient outcomes are still issues with digital health [48]. The internet and health industries, which have diverse research, design, testing, and implementation methods, complicate this problem. It is necessary to examine current design methodologies, weigh their advantages and implementation difficulties, and recommend a course of action that balances this intricate stakeholder group's needs. Integrating the limitations and affordances of digital design and health care, constructed equally around user delight and clinical efficacy, remains crucial regardless of how the end user is positioned—as a person, patient, or only user. Hence, we propose the following:

**User Experience (UX) significantly impacts Patient-Centric Design thinking (PCD):** According to Ouyang, user experience research techniques and user-centred design thinking have taken centre stage in interaction design [49]. So, it has become a common objective for designers and academics to investigate the transfer of user experience approaches and ideas to interaction design practice. The author suggested that visual, emotional colour theory can be one of the elements of design standards in immersive user experience research because it links emotional design and visual interaction design. So, we propose the following hypothesis:

**User Experience (UX) significantly impacts Quality by Design (QD):** Albayati highlighted the elements affecting the use of cryptocurrency wallets and investigated the causes of the high adoption and low usage rate of cryptocurrency wallets [50]. The author here demonstrated how User Experience (UX) affects usage levels and how trust affects the use of wallets. The author created a new model to understand better how real users behave when using cryptocurrency wallets. To grasp UX and incorporate trust as a crucial construct to appreciate the impact of user trust in Bitcoin wallets, this model merged the User Experience Questionnaire (UEQ) with usability. So, we propose our final hypothesis:

## Data analysis and findings

**Measurement model assessment:**

***Indicator reliability:***Indicator reliability is measured by squaring each outer loading available in the outer loading matrix in Table 1, except U1, UX1 and UX2, all of which are greater than 0.7. Since this is exploratory research so U1 is also considered coming higher than 0.4 [31] (Figure 1).

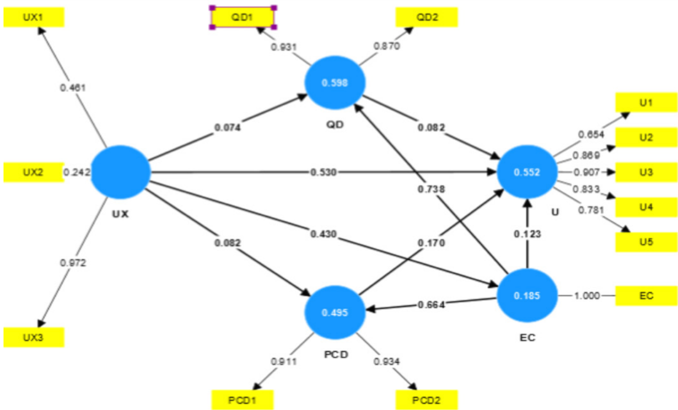


**Figure 1.** Structure Equation Modelling of MURPM-D through Smart PLS 4. **Note:** U=Usability; QD=Quality by Design; UX=User Experience; PCD=Patient-Centric Design

## Internal consistency reliability and convergent validity

In the case of Composite reliability (rho_a), all values are higher than 0.7, so it is evident that the composite scale passed the dependability test when all of the elements mentioned in Table 2 are viewed as a single scale. When the components are viewed as distinct scales, except UX, all Composite reliability (rho_c) values mentioned in Table 2 are higher than 0.7. Since this is exploratory research, UX is also acceptable as it is slightly more than 0.6.

In the case of Convergent validity, except UX (0.405), all AVE numbers mentioned in Table 3 are higher than 0.5 and accepted.

## Discriminant validity

**Heterotrait-Monotrait ratio (HTMT):** All the values of elements mentioned in Table 4 are below 0.90, so the Discriminant validity of the construct is well established.

**Fornell-Larcker criterion:** The square root of the AVE of each latent variable mentioned in Table 2 is greater than the correlations among the latent variables mentioned in the correlation matrix in Table 5.

**Table 5: Structural model assessment through Smart PLS 4.**

| | Original sample (0) | Sample mean (M) | Standard deviation (STDEV) | T statistics (O/STDEVI) | P values |
|---|---|---|---|---|---|
| EC->PCD | 0.664 | 0.656 | 0.078 | 8.570 | 0.000 |
| EC->QD | 0.739 | 0.735 | 0.088 | 8.424 | 0.000 |
| EC->U | 0.131 | 0.140 | 0.130 | 1.003 | 0.316 |
| PCD->U | 0.149 | 0.136 | 0.129 | 1.155 | 0.248 |
| QD->U | 0.081 | 0.086 | 0.174 | 0.464 | 0.643 |
| UX->EC | 0.429 | 0.432 | 0.109 | 3.931 | 0.000 |
| UX->PCD | 0.082 | 0.087 | 0.090 | 0.908 | 0.364 |
| UX->QD | 0.074 | 0.081 | 0.098 | 0.758 | 0.448 |
| UX->U | 0.538 | 0.536 | 0.075 | 7.220 | 0.000 |

### Structural model assessment

Following the assessment of the measurement model, the next step is evaluating the structural path for the evaluation of path coefficients (relationships amongst study constructs) and their statistical significance.

H1 evaluates whether Ethical Considerations (EC) significantly and positively affect Patient-Centric Design thinking (PCD). The results revealed that EC significantly and positively impacts PCD (O=0.664, t=8.570, $P \leq 0.001$). Hence, H1 was supported. H2 evaluates whether Ethical Considerations (EC) significantly and positively affect Quality by Design (QD). The results revealed that EC significantly and positively impacts QD (O=0.739, t=8.424, $P \leq 0.001$). Consequently, H2 was supported. H3 evaluates whether Ethical Consideration (EC) significantly and positively affect Usability (U). The results revealed that EC has an insignificant impact on U (O=0.131, t=1.003, $P \geq 0.001$). Hence H3 was not supported. H4 evaluates whether Patient-Centric Design thinking (PCD) significantly and positively affects Usability (U). The results revealed that PCD has an insignificant impact on U (O=0.149, t=1.155, $P \geq 0.001$). Hence H4 was not supported. H5 evaluates whether Quality by Design (QD) significantly and positively affects Usability (U). The results revealed that QD has an insignificant impact on U (O=0.081, t=0.464, $P \geq 0.001$). Hence H5 was not supported. H6 evaluates whether User Experience (UX) significantly and positively affects Ethical Consideration (EC). The results revealed that UX significantly and positively impacts EC (O=0.429, t=3.931, $P \leq 0.001$). Hence H6 was supported. H7 evaluates whether User Experience (UX) significantly and positively affects Patient-Centric Design thinking (PCD). The results revealed that UX has an insignificant impact on PCD (O=0.082, t=0.908, $P \geq 0.001$). Hence H7 was not supported. H8 evaluates whether User Experience (UX) significantly and positively affects Quality by Design (QD). The results revealed that UX has an insignificant impact on QD (O=0.074, t=0.758, $P \geq 0.001$). Hence H8 was not supported. H9 evaluates whether User Experience (UX) significantly and positively affects Usability (U). The results revealed that UX significantly and positively impacts U (O=0.538, t=7.220, $P \leq 0.001$). Hence H9 was supported. The results are presented in Table 3. The structural model is presented in Figure 2.

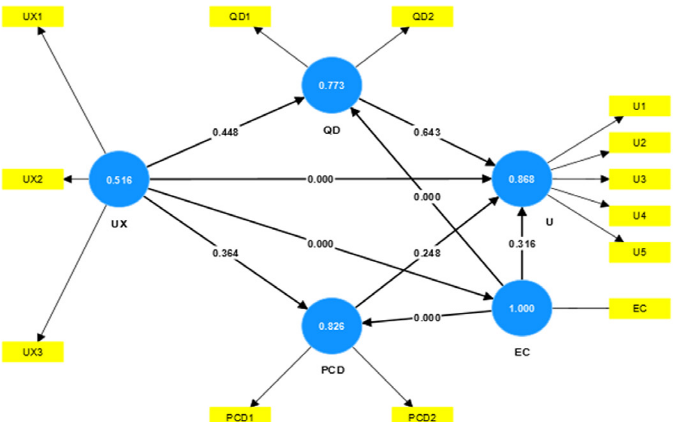


**Figure 2.** Structural Model; **Note:** U=Usability; QD=Quality by Design; UX=User Experience; PCD=Patient-Centric Design

## Results

### The proposed RPM-D architecture based on MURPM-D through SEM

A robust Remote Patient Monitoring for Diabetes (RPM-D) has been proposed. The basic outline is given in Figure 3. This architecture is evidence-based, and its feasibility is assessed from statistically significant Structural Equation Modelling through Smart PLS version 4. Few more additional information has been collected through the same survey tool and procedure, illustrated through graphs generated from the collected data available in Annexure III Figure 3. The most suitable form of AI-based Smart wearables/Smartwatch/Health or Fitness Apps/Remote Patient Monitoring systems is watches and Armbands. Different Health vitals that need to be monitored are as follows: Pulse Rate/ Pressure, Continuous Blood Pressure, Heart Rate Variability, Body Temperature, Blood Saturation, Cardiac output, Mean Arterial Pressure etc. The survey results also revealed that AI-based Smart wearables/Smartwatch/Health or Fitness Apps/ Remote Patient Monitoring systems solutions for the following: Chronic complex care monitoring, In-hospital monitoring, Pre and post-hospital monitoring, Ambulatory applications, Early warning score systems, Historical data graphs and trends with dashboard, Real-time measurement, and customizations etc. The most preferred operating system is Android, and the second most preferred is the iOS system. The most preferred connection parameters for uninterrupted service of RPM-D is WIFI, then Bluetooth Low Energy (BLE), next is IoT, IoMT, IoHT etc. For Ethical considerations, preference of RPM-D system should comply with all of the following: National Digital Health Mission (NDHM), Health Insurance Portability and Accountability Act (HIPPA), General Data Protection Regulation (GDPR), Healthcare Information Management Society (HIMS), WHO/ NMC/ICMR/DCI/Any other Regulatory bodies.

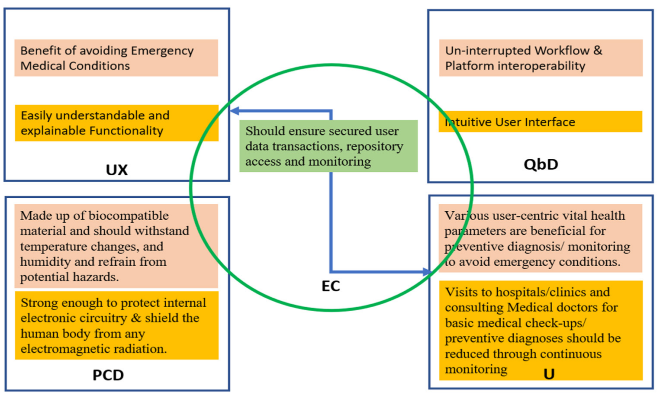


**Figure 3.** Basic Architectural needs for the sustainable framework of RPM-D.

## Conclusion

This study suggests an integrated architecture framework for remote patient monitoring for Diabetes (RPM-D). To meet the service needs of remote diabetes diagnosis and monitoring, a framework comprising sensors, IoT devices, the cloud, and the accompanying heterogeneous network architecture is needed. With thorough explanations of how it will address issues by combining User Experience (UX), Quality by Design (QbD), Patient Centric Design Thinking (PCD), and overall Ethical Considerations (EC), the architecture provided is promising and will likely significantly improve usability. For many stakeholders, this architecture was created with doctors, their chronic disease patients, particularly diabetic patients, and carers in mind. As a result, when the design is implemented, it will enable remote patient monitoring from small or nearby geographic areas without the inconvenience of the aforementioned societal problems. As a result, more people will have access to healthcare, lowering the risk of morbidity and mortality and lowering healthcare expenses. From this architecture, a remote patient monitoring system would eventually be created and used in a natural clinical environment.

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