DOKUZ EYLÜL UNIVERSITY
GRADUATE SCHOOL OF NATURAL AND APPLIED SCIENCES

DEVELOPING CLINICAL DECISION SUPPORT AND PATIENT MONITORING SYSTEM IN PRIMARY HEALTH CARE WITH CASE STUDIES

by
Özge KART

June, 2018
İZMİR

DEVELOPING CLINICAL DECISION SUPPORT AND PATIENT MONITORING SYSTEM IN PRIMARY HEALTH CARE WITH CASE STUDIES

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Ph.D. THESIS EXAMINATION RESULT FORM

We have read the thesis entitled **"DEVELOPING CLINICAL DECISION SUPPORT AND PATIENT MONITORING SYSTEM IN PRIMARY HEALTH CARE WITH CASE STUDIES"** completed by **ÖZGE KART** under supervision of **PROF. DR. ALP KUT** and we certify that in our opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Doctor of Philosophy.

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ABSTRACT

Physicians' guidelines utilization rates for diagnosis, treatment and monitoring of diabetes mellitus (DM) and hypertension (HT) is very low. Time constraints, patient overpopulation and complex guidelines require alternative solutions. Rapidly evolving e-health technology combined with clinical decision support systems provides an effective solution to these problems.

The purpose of the study is to develop a user-friendly, comprehensive, fully integrated web and mobile-based clinical decision support and monitoring system (CDSMS) for the screening, diagnosis, treatment and monitoring of DM and HT diseases for the use of physicians and patients in primary care.

CDSMS is based on evidence-based guidelines for DM and HT diseases. A web and mobile-based application has been developed. The physician remotely monitors the patient data collected from mobile application.

The developed CDSMS has been tested in two stages. In the first stage, the usability, understandability and adequacy of the application has been determined. Three family physicians have used the developed application for their 15 DM patients. Then, necessary improvements in the application have been made in accordance with the physician feedback.

In the second phase, a parallel single blind randomized controlled trial has been implemented. Using CDSMS, DM diagnosed patients recruited for trial by their primary care physicians. Eligible participants were assigned to intervention and control groups with simple randomization. Seventy-five patients were assigned to intervention group and 226 patients were assigned to control group. In the

intervention group, the system made recommendations on diagnosis, treatment and patient monitoring. These recommendations were implemented at the physician's discretion. In the control group, physicians treated DM patients without using CDSMS. Patients in both groups have been monitored for 6 months. Patient data has been compared between 0th and 6th month of the study.

In conclusion, this study aims to decrease the rate of morbidity and mortality as well as number of visits to healthcare centers by providing continuous monitoring and effective treatment to patients. The developed system using evidence-based guidelines is the first example among the medical expertise fields providing health services to DM patients.

Keywords: diabetes, hypertension, clinical decision support, screening, diagnosis, treatment, monitoring, e-health, m-health

BİRİNCİ BASAMAK SAĞLIK HİZMETLERİNDE KLİNİK KARAR DESTEK VE HASTA İZLEME SİSTEMİ GELİŞTİRİLMESİ VE ÖRNEK UYGULAMALAR

ÖZ

Hekimlerin, hipertansiyon (HT) ve diyabet (DM) hastalıklarının tanı tedavi ve izlem rehberlerini kullanım oranları çok düşüktür. Zaman kısıtlılığı, hasta yoğunluğu, rehberlerin karmaşık olması nedeniyle rehberlerin kullanımı için farklı çözümlerin bulunması gereklidir. Hızla gelişen e-sağlık teknolojisi, klinik karar destek ve izleme sistemi açısından bu tür sorunlara çözüm olabilecektir.

Çalışmanın amacı, birinci basamak sağlık hizmetlerinde hekim ve hastanın kullanımı için, HT ve DM hastalıklarını tarama, tanı, tedavi, takip amaçlı web ve mobil web tabanlı kullanıcı dostu klinik karar destek ve izlem sistemi (KKDİS) geliştirerek etkinliğini saptamaktır.

KKDİS, HT ve DM hastalıkları için kanıta dayalı rehberler kullanılarak web tabanlı olarak geliştirilmiştir. Mobil uygulamayla ise hastaların ölçüm değerlerinin toplanarak uzaktan izlenmesi sağlanabilmektedir.

Geliştirilen uygulamanın test edilmesi iki aşamada yapılmıştır. Birinci aşamada uygulamanın kullanılabilirliğini, anlaşılırlığını ve uygunluğunu saptamak için geliştirilen uygulamayı üç aile hekimi, polikliniklerine başvuran 15 DM hastasında kullanmışlardır. Alınan geribildirimler doğrultusunda programda gerekli düzeltmeler yapılmıştır.

İkinci aşamada ise KKDİS'nin validasyonu yapılmıştır. KKDİS kullanılarak yapılan tarama sonucuna göre DM ve/veya HT saptanan hastalar deneysel çalışmaya alınmıştır. Randomize kontrollü çalışma olarak yürütülen çalışmada basit randomizasyonla 75 hasta müdahale ve 226 hasta kontrol grubuna alınmıştır. Müdahale grubunda tanı, tedavi ve izlem sistem önerileri, sonuç kararı hekimin

vereceği şekilde yürütülmüştür. Kontrol grubunda ise hekim HT ve DM hastalarını genel rutinindeki şekilde hasta yönetimine devam etmiştir. Her iki gruptaki hastalar 6 ay süreyle izlenmiştir. 0. ve 6.ay verileri karşılaştırılmıştır.

Sonuç olarak, bu uygulamayla hastaların sürekli izlemi ve etkin tedavi almalarını sağlayarak morbidite, mortalite ve sağlık kurumlarına başvuru oranını azaltılması hedeflenmektedir. Hastanın ilaç kullanımı ve yaşam tarzı değişikliği konularındaki tedavi uyumu sağlanacaktır. Türkiye'de HT ve DM hastaları için birinci basamağa uygun, kanıta dayalı rehberleri kullanan ilk klinik karar destek sistemi örneğidir.

Anahtar kelimeler: diyabet, hipertansiyon, klinik karar destek, tarama, tanı, tedavi, takip, e-sağlık, m-sağlık

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CHAPTER ONE
INTRODUCTION

1.1 Overview

Diabetes mellitus (DM) and Hypertension (HT) are among the leading causes of morbidity and mortality in chronic diseases in our country as well as internationally. In the Turkish Hypertension Prevalence Study (PATENT2) conducted in 2012, the prevalence of hypertension was found to be 30.3%. The awareness rate of hypertension in all age groups was 54.7%. Unfortunately, only 28.7% of hypertensive patients were under control (Türk Hipertansiyon ve Böbrek Hastalıkları Derneği, 2012).

The prevalence of diabetes in Turkey according to TURDEP II study results were 13.7%. HbA1c is accepted as a marker for glycemic control criterion. Ratio of diabetic patients whose blood glucose is regulated is very low (TURDEP-II Çalışma Grubu, 2002). According to a study, the rate of diabetic patients whose HbA1c value is <7% were found only 30.1% (Ilkova et al., 2011).

A study from the National Burden of Disease reports that cardiovascular diseases and diabetes rank first and ninth among the causes of death with mortality rates of 47.7%, and 2.2% respectively (TC Sağlık Bakanlığı, 2013). In 2009, The World Health Organization reported that the top three of the risk factors for mortality are, in order, high blood pressure, smoking and high blood glucose (WHO, 2009). Diabetes and hypertension have high prevalence and continues to increase worldwide over time.

Diabetes is one of the highest cardiovascular disease risk factors. If the disease is taken under control, morbidity and mortality rates of society reduce. Despite the high rate of DM and HT prevalence, diagnosis of the disease is still around 50%. The diagnosis rates should be increased first to reduce morbidity and mortality caused by the DM and HT diseases. DM and HT prevalence studies in Turkey have shown that

halves rule is valid for awareness, treatment and control rates of the diseases (TURDEP-II Çalışma Grubu, 2002) (Türk Hipertansiyon ve Böbrek Hastalıkları Derneği, 2012).

Today, the purpose of chronic illness treatment is not to heal the patient, but to enhance the adherence of the individual to the treatment program and to promote the life quality by cooperation. For this reason, in recent years, the importance of protecting, maintaining and developing health has been emphasized over the treatment of the disease, thus nurturing the concept of "self-care" (Aggleton & Chalmers, 1985).

DM and HT management guidelines are prepared on the basis of evidence based studies conducted by experts both at the international and national levels from all over the world. In DM and HT management guidelines, the standards for diagnosing are specified and the requirements for differential diagnosis are systematized (Türkiye Endokrinoloji ve Metabolizma Derneği Diabetes Mellitus Çalışma ve Eğitim Grubu, 2013). Then the disease is classified according to the patient's history, physical examination and laboratory data.

The guidelines suggest which patient risk factors should be evaluated and which tests should be completed. After diagnosis and differential diagnosis, treatment alternatives depending on the patient's staging are suggested to physicians based on the results of the evidence-based studies. In these guidelines, treatment and follow-up process according to the diagnosis and prognosis are located systematically (Türkiye Endokrinoloji ve Metabolizma Derneği Diabetes Mellitus Çalışma ve Eğitim Grubu, 2013; American Diabetes Association, 2015; James et al., 2014; Mancia et al., 2013).

Physicians' guideline usege rate in Turkey, as well as internationally, is very low. A study conducted in Turkey showed that diabetic patients are not treated according to current guidelines (Damci, Kultursay, Oguz, Pehlivanoglu, & Tokgozoglu, 2004). Another study conducted in the primary care reported that utilization of HT guidelines by family physicians is very low.

Periodic health care is a monitoring program formatted by risk factors, through screening, examination and testing of healthy people, counseling and health education. The program is evidence based, effective, feasible and acceptable. In this evidence based program, screening, case detection, immunization, chemoprophylaxis and counseling are defined clearly according to people's age, sex and risk factors. Institutions that provide primary care carry out periodic health care services. Established guidelines require healthy adults to be periodically screened for health risk assessments. The blood pressure of healthy people should be measured annually from the age of 18 on a regular basis. HbA1C test must be applied once every three to five years to patients with high risk score and once a year to those with very high score (Canadian Task Force on Preventive Health Care, n.d.).

Primary care providers play a vital role in the diagnosis, treatment and control of DM and HT diseases. World Health Organization states that primary health care has a key role in reducing the morbidity and mortality rates of chronic diseases. Strengthening primary care is on the agenda of all countries for ensuring the control of chronic diseases. Therefore in primary care, adapting physician's approach to current DM and HT management guidelines and developing a standard approach will provide significant gains in diabetes and hypertension control.

1.2 Motivation

Physicians' guidelines utilization rates for diagnosis, treatment and monitoring of diabetes mellitus (DM) and hypertension (HT) is very low. Time constraints, patient overpopulation and complex guidelines require alternative solutions. Rapidly evolving e-health technology combined with clinical decision support and monitoring systems provides an effective solution to these problems.

Machine learning methods help to create useful models for various purposes from making predictions for the future to understanding hidden patterns or relations in data. A machine learning based clinical decision support system is also aimed to be developed using patient data.

Millions of people around the world are living with chronic diseases such as diabetes mellitus and hypertension. The cost of diagnosis and treatment of these diseases are very high. At this point, monitoring the vital data such as glucose, blood pressure and exercise data by the physician is very important. Although these data can be monitored in the hospital or outpatient setting, it is both costly and difficult to implement because of the constant follow-up and life standards of the patients. Tele monitoring systems enable to monitor blood glucose, blood pressure, and exercise data daily within the time period determined by the physician. The family physician can remotely monitor the data collected instantaneously and suggest a change in the treatment plan or lifestyle according to the patient's condition.

1.3 Aim of Thesis

The purpose of the study is to develop a user-friendly, comprehensive, fully integrated web and mobile-based clinical decision support and monitoring system (CDSMS) for the screening, diagnosis, treatment and monitoring of DM and HT diseases for the use of physicians and patients in primary care and to determine the effectiveness of the system.

This dissertation shows applications of both a rule based decision support system and a machine learning based decision support system. The rule based clinical decision support system has been developed based on the rules obtained from evidence-based guidelines (American Diabetes Association, 2015) (James et al., 2014). The web based system provides screening, diagnosis and treatment suggestions to primary care physicians. In the machine learning based decision support system, the knowledge has been gathered from patient data. Time series analysis and decision tree methods were used in the system for different purposes. Time series analysis is used to predict a patient’s blood glucose and blood pressure values in next ten days by analyzing the past measurement values. Decision tree model is used to predict diabetes risk of a patient.

For (tele) monitoring system, a mobile health application has been developed to collect patients' blood pressure and blood glucose measures, physical activity information. The patient data collected from telemonitoring systam is presented to family physician by a web application.

1.4 Thesis Organization

The thesis consists of seven chapters. In this chapter, motivation and aim of the thesis and the contribution to the field is stated. The rest of the thesis is given in the following pharagraphs.

Chapter 2 presents a literature survey on rule based clinical decision support systems, machine learning based clinical decision support systems and mobile health systems.

Chapter 3 explains material and methods used in the study. Machine learning methods used for clinical decision support system are explained. The tools and libraries used for system development is detailed.

Chapter 4 presents system architecture and database design of the Clinical decision support system for screening diagnosis, treatment and follow-up of diabetes and hypertension patients in primary care units. The developed web based application is detailed by giving some sample screens.

Chapter 5 presents mobile health application. The developed mobile application is detailed by giving some sample screens.

In chapter 6, data analysis of conducted experiment is detailed. Experimental results are demonstrated.

Finally, conclusions and future directions of the thesis are presented in Chapter 7.

CHAPTER TWO
RELATED WORKS

This chapter starts with the clinical decision support systems. Rule based and machine learning based systems are explained in the following subsections. In section 2.2, existing mobile health applications are explained.

2.1 Clinical Decision Support Systems

The concept of decision support is broadly acknowledged in clinical care, beginning from a basic database inquiry to complex treatment suggestions. The development of clinical decision support systems (CDSSs) is still a current issue. The knowledge of the CDDSs is provided from scientific literature, local and practice based evidence (Sim, et al., 2001).

Utilization of evidence based guidelines in computerized decision support systems are expected to improve the acceptance and implementation of guidelines in daily practice. The reason for this is the actions and the evaluations of clinicians can be monitored. The system's recommendations are also presented to the users.

De Clercq, Blom, Korsten, & Hasman, (2004) identified four areas for the process of developing guideline-based decision support systems. These are:

1. Guideline modeling and representation
2. Guideline acquisition
3. Guideline verification and testing
4. Guideline execution

Guideline modeling and representation must obtain a profound comprehension of clinical procedures, addressed by the guideline, an exact and clear depiction of the guideline and a means for automatic parsers to execute guidelines to facilitate decision support process.

Guideline acquisition is a process that facilitates the knowledge acquisition process directly from field experts. Guideline verification and testing process targets to make sure the machine-interpretable guideline is unambiguous and both syntactically and semantically correct. In addition, guidelines must be tested with existing patient data.

The last area is guideline execution. It involves execution time and ability of running in multiple clinical domains and different modes.

An alternative way to guideline-based approach is machine learning algorithms such as artificial neural networks or support vector machines. Lisboa, P. J., & Taktak, A. F. (2006) has done a systematic review of these machine learning based approaches about decision support in cancer. Unlike the process from guideline modeling to execution, machine learning methods extract knowledge automatically from clinical data and obtain decision support by using this knowledge.

CDSSs can be in several areas of medicine to provide medical decision support. There are medication-related CDSSs (Kuperman et al., 2007) for drug-allergy and drug-drug interaction checking, basic dosing guidance, formulary decision support, and duplicate therapy checking. Moreover dosing support for renal insufficiency and geriatric patients, guidance for medication-related laboratory testing, drug-pregnancy checking, and drug- disease contraindication checking.

CDSSs appear to be extremely useful in supporting clinical decisions, yet it is hard to make healthcare specialists really utilize them. According to Bates et al. (2003), there are ten rules for facilitating implementation of CDSSs. These rules are: 1. speed of decision support process; 2. anticipate needs and deliver in real time; 3. fit into the user's workflow; 4. little things can make a big difference (usability issues); 5. recognize that physicians will strongly resist stopping (suggestions); 6. changing direction is easier than stopping; 7. simple interventions work best; 8. ask for additional information only when you really need it; 9. monitor impact, get feedback and respond; 10. manage and maintain your knowledge-based systems.

Roshanov et al. conducted a decision-maker-researcher partnership systematic review. They searched important databases and reference lists for potentially eligible articles published up to January 2010. The aim of the study was to determine if CDSSs improve the processes of chronic care (such as diagnosis, treatment, and monitoring of a disease) and associated patient outcomes. They indicated in their review that CDSSs can improve chronic disease management processes and, in some cases, patient outcomes. They showed that diabetes care trials presented the most promising results (Roshanov et al., 2011).

Kantor et al. (2011), analyzed CDSSs for diabetes in United States. They concentrated on diabetes since it is regular in the United States. Their study includes visit checking of both clinical indications and lab tests. It has a treatment and has a course that can be influenced by preventive health measures. They revealed that as healthcare specialists in the United States move towards implementing electronic records and clinical decision support, guarantee that decision support depends on evidence-based guidelines yet takes into consideration local variation and institution standards.

2.1.1 Rule Based Clinical Decision Support Systems in Primary Care

There are variety of uses of rule based CDSS in primary care such as management of hypertension, depression, medication reviews and diabetes diagnosis.

Anchala, Di Angelantonio, Prabhakaran, & Franco (2013), developed a clinical decision support system based on hypertension guidelines for staging and risk stratification of hypertension. They aimed to produce evidence based recommendations on drug management and life style advice for hypertensive patients in order to enhance management of hypertensive patients in primary care. As a result, sensitivity and specificity of the DSS were 83.33% and 85.71% respectively when compared with independent experts.

In a study about development of a clinical decision support system for treatment of depression, the CDSS algorithm, utilizing measurement-based care, was better than normal care for patients with major depressive disorder in primary care settings. Patients treated by doctors who use CDSS had prominent symptom reduction than patients treated with regular care ($P < .001$) (Kurian et al., 2009).

Meulendijk, Spruit, Jansen, Numans, & Brinkkemper (2015) developed a stand-alone web-based decision support system called STRIPA for medication reviews in Primary Care. It provided recommendations to physicians during the pharmacotherapeutic analysis of patients' health records. Experimental results of the prototype by general practitioners and pharmacists presented that users' performance increased when medication was optimized with the CDSS.

In a study, a decision support system has been proposed for diabetes diagnosis. It asks some questions about the signs, symptoms and risk factors to the user. He/she replies as yes or no in a user interactive and menu driven interface. According to the answer the system makes a decision about the possibility of the disease and the stage of the disease such as slight, moderate, high, very high, diabetic or not. (Rahaman, 2012)

Chen, Goh & Chong (2013) conducted a study which aims to develop a clinical decision support system to support evidence based practice. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. The CDSS proposes possible disease according to the results of Complete Blood Count test. It provides online medical literatures for the treatment of these suggested diseases.

2.1.2 Machine Learning Based Clinical Decision Support Systems

The usage of machine learning techniques in clinical decision support systems are less common (Bali, Feng, Burstein & Dwivedi, 2005). Most methods for clinical decision support are based on rule induction. These methods are inferred from

deriving and evaluating rules, and optimizing the performance of these rules. On the other hand, machine learning algorithms can be used to provide clinical decision support with a proper design and implementation. In machine learning, knowledge discovery concept is essential. Real world problems can be modelled by decision functions, mathematical and statistical equations etc. It is possible to provide future predictions or other useful information with machine learning methods.

Aleksovska-Stojkovska & Loskovska (2013) presented the possibility of using data mining methods in extracting patient specific rules from the individual data collected from asthmatic children. The extracted rules are used to support the clinical decision process. These rules are obtained from association rule mining process and stored in an individual patient knowledge base.

Anooj (2012) proposed a weighted fuzzy rule-based clinical decision support system (CDSS) for the diagnosis of heart disease. Fuzzy rules are created automatically and are weighted according to their significance of the attribute weightage. Before carrying out prediction on the designed fuzzy-based CDSS, these weighted fuzzy rules are applied on the rule base of the fuzzy system. They tested their model by using a dataset from UCI machine learning repository. The results showed that the proposed clinical decision support system improved risk prediction significantly compared with the network-based system in terms of accuracy, sensitivity and specificity.

Kumar, D. S., Sathyadevi, G., & Sivanesh, S. (2011) presented a study which is the development and evaluation of a Clinical Decision Support System for the treatment of patients with heart disease, diabetes and hepatitis. They aimed to classify the diseases and to compare the attribute selection measure algorithms such as ID3, C4.5 and CART. The results showed that making clinical application more accessible will provide great advance in healing coronary artery disease, hepatitis and diabetes. A survey has been made on the ID3, C4.5 and CART decision tree algorithms towards their steps of processing data and complexity of running data. At

last, among the three algorithms, the CART algorithm is stated to have better performance of rules generated and accuracy.

A new diagnosis and treatment system was proposed by Oguntimilehin, Adetunmbi & Olatunji (2014) for providing decision support to typhoid fever cases. A decision tree algorithm was used on labeled set of typhoid fever conditional variables to recommend a decision. The classifiers for the diagnosis of typhoid fever and treatments were obtained in accordance with the severity level of the disease. The accuracy of the system was computed on the training set and testing set with the detection rates of 100% and 95% successively.

Zhang, Fong, Fiaidhi & Mohammed (2012) described a clinical-support-system based on data stream mining technology. They introduced a new system that is able to analyze medical data streams and make real-time prediction. The proposed system is based on the stream mining algorithm called very fast decision tree (VFDT). The VFDT is able to use pointers to make the decision tree remember the mapping relationship between leaf nodes and the history records. This way eliminates the need for the offline clustering process and decreases the resource consumption of the system.

2.2 Mobile Health Systems

Mobile technologies are getting important for individual-level support to health care users and promising platform for health interventions. In recent years, researchers have been using mobile phones for supporting physical activity and healthy diets (Brown, Chetty, Grimes, & Harmon, 2006), for symptom monitoring in asthma (Holtz & Whitten, 2009) and heart disease (Villalba et al., 2009), for sending patients reminders about upcoming appointments, for supporting smoking cessation (Hassandra, 2015), and for a range of other health problems (Klasnja & Pratt, 2012).

Villalba et al. (2009), presented the design and development of a mobile system to improve the life quality of heart disease patients. A mobile device receives data

from all measuring wearable sensors and devices via Bluetooth and processes the received data for encouraging patients in their daily healthcare. The system consists of a processing server (that analyzes all data), database, and a web portal that provides ubiquitous access to the professionals. All received data, raw signals, and notifications are sent to the back end for further processing and management. Back-end communication needs the user's mobile device to have (GPRS) or universal mobile telecommunications system (UMTS) connection to enable a client for a Web service in the server side via secure channels such as HTTPS and SSL.

A mobile health application was developed to be used as an encouraging tool for quitters to manage their cigarette cravings. They claimed that if the application is shown to be effective, their work will obtain evidence for the use of the application as a support tool for people who are trying to manage cravings during smoking cessation programs (Hassandra, 2015).

A study was conducted to determine the usability of mobile phones as a tool for clinic-based face-to-face data collection for pregnant women living with HIV. Obtaining complete and correct data from rural clinical sites was a major challenge. The MPAPI survey platform was used in that study. In the mobile application, it displayed and saved surveys. With using this, 708 interviews with 520 participants was done and 512 participants took part in mobile questionnaire. Then their experince was asked to them. 94.7% of them had a positive opinion on it and only 0.6% of them had negative. When comparing mobile and pen-and-paper questionnaries, 2.7% of participants chose pen-and-paper questionnaries. According to some participants, using mobile phone was more practical and more secured. As a result, mobile phones were found useful for data collection (Van Heerden, Norris, Tollman, Richter, & Rotheram-Borus, 2013).

Another study has been done to evaluate effectiveness of a mobile phone as a supporter in smoking cessation effort. To achieve this, firstly an application was developed. The application provided recording progress of smoking cessation plan for users and informed them about harms of smoking. It also offered an alternative to

users when they want to smoke. For example, it offered a game which entertained user or gave messages to avoid smoking. This application was tested with the young people who use mobile phones frequently, smoke more than 10 cigarettes per day and have high motivation to stop smoking. These people received 6-month smoking cessation programme including support of this application. Measurements and necessary informations were all recorded. At the end of study, it was come out that these records provided useful information for next studies and the application can be a useful tool for smoking cessation (Valdivieso-López et al., 2013).

Gay, Leijdekkers & Barin (2009) developed a mobile application for rehabilitation which supports users to follow and monitor their exercises. Their proposed system consisted of a mobile phone and wireless sensors. There were multiple sensors for different purposes. It can be wearable or an external device and it transmits data to the mobile phone for analysis. After the analysis, a feedback was given to the user. The data was also sent to the health care data server for remote monitoring and can be examined through it by a health care specialist. Thus, an individualized advice can be given by specialists. The application can also be personalized according to user and reminders for measurements can be set. It was tested on cardiac patients and found useful and acceptable by patients.

A research including patients with ages between 14 and 24 has been conducted to determine effectiveness of a proposed mobile application for assessment and management of youth mental health problems. It involved analyzing some criteria such as mood, stress, activities, alcohol use. This information was also sent to general practitioners (GP) for medical examination. The application was tested with intervention and control groups of participants. In intervention group, parameters like mood, stress, daily activities were controlled and in control group, only daily activities were controlled. These 2 groups were observed by GPs for 2-4 weeks. Some measurements were made during this observation process. These measurements were depression, anxiety, stress scale and emotional self-awareness scale (ESA). The results showed that the self-monitoring intervention program significantly increased ESA until six weeks after the program was completed. In

conclusion, it was found that the mobile application was very effective and provided improved mental health of the patients (Reid, et al., 2011).

Meankaew et al. (2010) aimed to determine the effectiveness of using mobile phones with a routine malaria prevention and control program. The module which was used to monitor treatment of malaria included combination of web-based and mobile technologies. It was developed instead of the paper-based activities which were used before. Treatment details of patient's were recorded in the malaria database. After the monitoring program was scheduled, the status of the patient was updated during routine home visits using this module. It also provided statistics for analysis of disease. The application was installed on mobile phones for easily usage. Thus, healthcare personnel can use it efficiently to perform their routine tasks.

A study was conducted to analyze the benefits of monitoring of patients symptoms from mobile phone. An application which cancer patients can enter their symptom data was used. After patient entered data, it was sent to the remote computer. It was analyzed and displayed on web page to nurses for examining and a feedback message was sent to patient's phone automatically. If there was an important situation to concern, red or amber alert related to the severity was generated and it warned the nurse. After that, nurse contacted patient to inform about it. Six patients were used for trial of this application. Nurse decided what to do with examining data and alerts of patients. All patients gave a positive opinion. They found the application useful and beneficial for their health. The application was effective (Weaver et al., 2007).

In addition, various kinds of m-health applications was developed for other purposes such as enabling users to log and chart data about their diet (Denning et al., 2009; Tsai et al., 2007) , exercise (Consolvo et al., 2008; Mattila et al., 2008), blood glucose levels (Mamykina & Mynatt, 2008), and other health-related behaviors and measures (Praveen et al., 2013; Desveaux et al., 2016; Parmanto, Pramana, Yu, Fairman, & Dicianno, 2015; Hardinge et al., 2015); patient terminals for tele-monitoring of conditions such as hypertension (Logan et al., 2007) and chronic heart

failure (Scherr et al., 2006); applications that receive data from pedometers, blood pressure monitors and other devices (Mohan, Marin, Sultan, & Deen, 2008).

On the other hand, some researchers (Becker, Sugumaran, & Pannu, 2004) developed other diabetes support systems using mobile phones; in which the user inputs information regarding his/her daily measures rather than using sensors.

CHAPTER THREE
MATERIAL AND METHODS

This chapter starts with the definition of Decision Support System and Machine Learning concepts. Two machine learning methods, time series analysis and decision tree, which are used in this thesis, are explained. In the last section, libraries, software and database tools that have been used in this study are explained.

3.1 Decision Support Systems

Decision Support System (DSS) is a sub-category of computer programs, which supports decision-making activities within an organization. It means an interactive software-based knowledge source and a mechanism supposed to assist decision makers compile helpful information from, documents, personal expertise, and/or business models to point out and solve issues.

Experiences of domain specialists and literature constitutes of the knowledge source of decision support systems. There are many decision support systems developed for assisting clinicians. These systems store and use knowledge when they receive a query. The knowledge of these software programs is mostly based on the direct input from clinicians such as rule sets.

Others utilize methods like machine learning algorithms and case-based reasoning for knowledge extraction. Hence, they are solely based on data. Machine learning based systems are able to avoid the congestion of knowledge acquisition as the knowledge is obtained directly from raw data. What is more, machine learning-based decision support systems can be easily updated by only including new data.

This dissertation shows an application of both a rule based and a machine learning based decision support system to show the effectiveness of clinical decision support systems in screening, diagnosis, treatment and follow-up of diabetes and hypertension. The proposed rule based clinical decision support system provides

decision support to the physicians by extracting rules from evidence based diabetes guidelines. The ML based clinical decision support system gathers knowledge automatically and uses optimization methods to return appropriate answers to queries.

3.2 Machine Learning

Machine Learning is a subfield of artificial intelligence. It means programming computers to optimize a performance criterion using example data or past experience or finding patterns in data. Machine learning methods are known as knowledge discovery. These methods aim to model real world problems in the form of decision trees, rules or mathematical formulas. They can make good predictions and extract useful information. This dissertation applies machine learning algorithms to discover useful information for diabetes patients.

Machine learning algorithms are often categorized as being supervised or unsupervised.

3.2.1 Unsupervised Learning

In unsupervised learning, the model learns from input data without labeled responses. The most common unsupervised learning method is cluster analysis, which groups data based on their similarities.

3.2.2 Supervised Learning

In supervised learning, training is done with labeled data which means cases that have pre-known output. Decision functions extracted from training operation have ability to turn over attribute values to predicted labels. The prediction performance is measured by comparing with these correct labels. The name of this process is validation.

While validating a model, a dataset is divided into two subsets. One dataset is used for training and the other one is used for testing. N-fold cross validation is a common method as it has low variance, low bias, and can be easily computed. In n-fold cross validation, *n-1* subset of the dataset is used for training and 1 subset is for testing. This process repeats n times so as each n subset is used once for testing.

The decision functions of supervised learning methods constitute the knowledge that is extracted from data. So if it is designed properly the functions can be applied to many problems. This dissertation involves the usage of decision functions in clinical decision making and introduces some methods of machine learning that relate to the clinical decision support system.

3.2.3 Time Series Analysis

Time Series is a time-based or chronological collection of observations on an interested variable. If a variable is measured as a sequence in time over a fixed interval, the collected data is in the form of a time series.

Time series analysis is the usage of statistical techniques to model and provide an explanation for a time based series of data points. Time series forecasting is the method of using a model to make predictions for future events based totally on regarded past events. Unlike other data, time series data has a natural temporal ordering. Therefore, time series analysis distincts from other typical data mining/ machine learning applications where each data point is independent in the concept to be learned. The order of data points is not important. Time series prediction proposes algorithms for which past time series data, mostly sequences of data points associated to uniform time interval, are used to build models to predict future data points of the sequence (Kosorus, H., Hönigl, J., and Küng, 2011).

In this study, it is aimed to predict future values of blood glucose of patients by using time series analysis.

3.2.4 Decision Trees

Decision tree is a classification method commonly used in data mining tasks. The aim of decision tree is to create a model that predicts the value of a target class for an unseen data point based on various input features of past data. Decision trees have some advantages among the data mining methods. They are easy to understand, implement and interpret and do not require prior knowledge. They can handle numerical and categorical data.

A decision tree is a tree in which each branch node represents a choice between a number of alternatives, and each leaf node represents a decision. When building a decision tree, there are two important issues: the growth of the tree to precisely categorize the training dataset, and the pruning stage, when redundant nodes and branches are eliminated in order to improve classification accuracy. Generally, each decision tree is a rule set. Decision tree partitions the training sets into smaller subsets recursively until all the subsets belong to a single class (Mitchell, T. M., 1997).

3.3 Tools and Libraries

The functions of the software are developed based on Service Oriented Architecture. The web-based software is developed using Visual Studio 2015 environment. MVC (Model, View, Controller) is used as software architecture pattern. The software is developed with C# programming language and using Restful web services. The database management system is Microsoft SQL Server. Private cloud technology is used to implement the portal. Therefore, the capacity can be increased easier if necessary.

Software framework services constitute the technological infrastructure of the software that all other modules use. The services that are included in the software framework ensure the establishment of relations between objects and the automatic creation of class structures related to the objects. They also allow communication

with database and running various database queries. System architecture is shown in Figure 3.1.

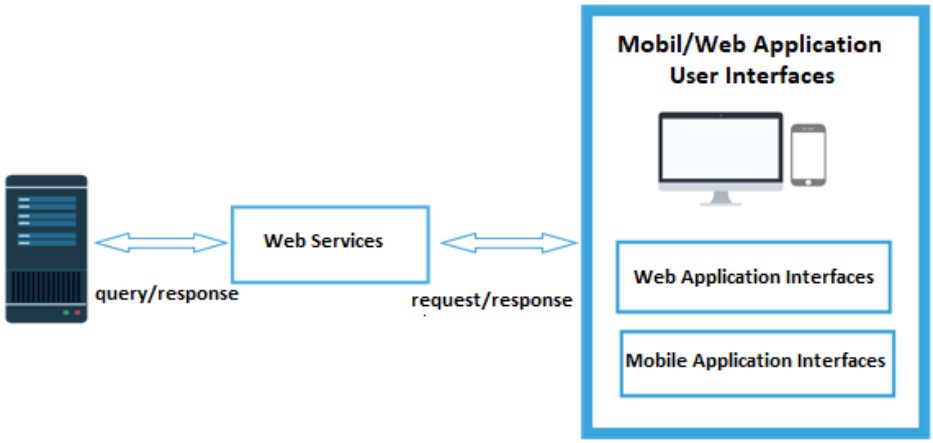


Figure 3.1 System architecture

The mobile health application part of the project is developed for Android devices. Android Studio and SDK tools are used for development.

In machine learning based clinical decision support system, decision tree and time series forecasting models have been developed using Waikato Environment for Knowledge Analysis (WEKA). WEKA is free software with a general public license, which includes a large number of methods, and algorithms for data mining, including data preprocessing, classification, clustering, regression, visualization and feature selection. Weka (>= 3.7.3) has a time series analysis environment which provides to develop, evaluate and visualize forecasting models.

CHAPTER FOUR
WEB BASED CLINICAL DECISION SUPPORT SYSTEM

The aim of the study is to develop a user-friendly, comprehensive, fully integrated web and mobile-based Clinical Decision Support and Monitoring System (CDSMS) for DM and HT diseases screening, diagnosis, treatment and monitoring. The system is developed for the use of physicians and patients in primary care. In this direction;

-Supporting physicians in making the right clinical decision,

-Use of mobile health technology for monitoring patients and medication adherence of patients,

-Providing periodic health care for patients,

-Providing consultancy in the electronic environment are the main objectives of the system.

Thus, this system is expected to reduce the rate of morbidity, mortality and health care applications due to this disease. Health costs may decrease. Lifestyle change of patients is supported. The proposed system integrates information technologies into patient care and follow-up in primary health care.

The system is developed for Diabetes Mellitus and Hypertension diseases, which are among the chronical diseases with highest morbidity in Turkey. Providing primary health care services, which is preventive, curative and health promoting services are aimed with this system. The family physicians who use this system can diagnose DM and HT diseases early. They can monitor their DM and HT patients more regularly.

The decision support system is developed as web application for the family physicians. Physicians can input patient information to the developed web application, display patient data, and receive support for patient treatment using rule-based decision support system.

The mobile health application is developed for the use of patients. The developed application collects patients' blood glucose, blood pressure, exercise, medication adherence information and presents these data to their family physicians. The application also has reminder for blood glucose and/or blood pressure measurement, medication times, exercise, etc. Family physicians schedule a plan for each individual patient and mobile application notify the users at appropriate times to carry out the plan regularly.

The system also allows patients and physicians to communicate easily by sending and receiving messages from web and mobile application. Overall system design is shown in Figure 4.1

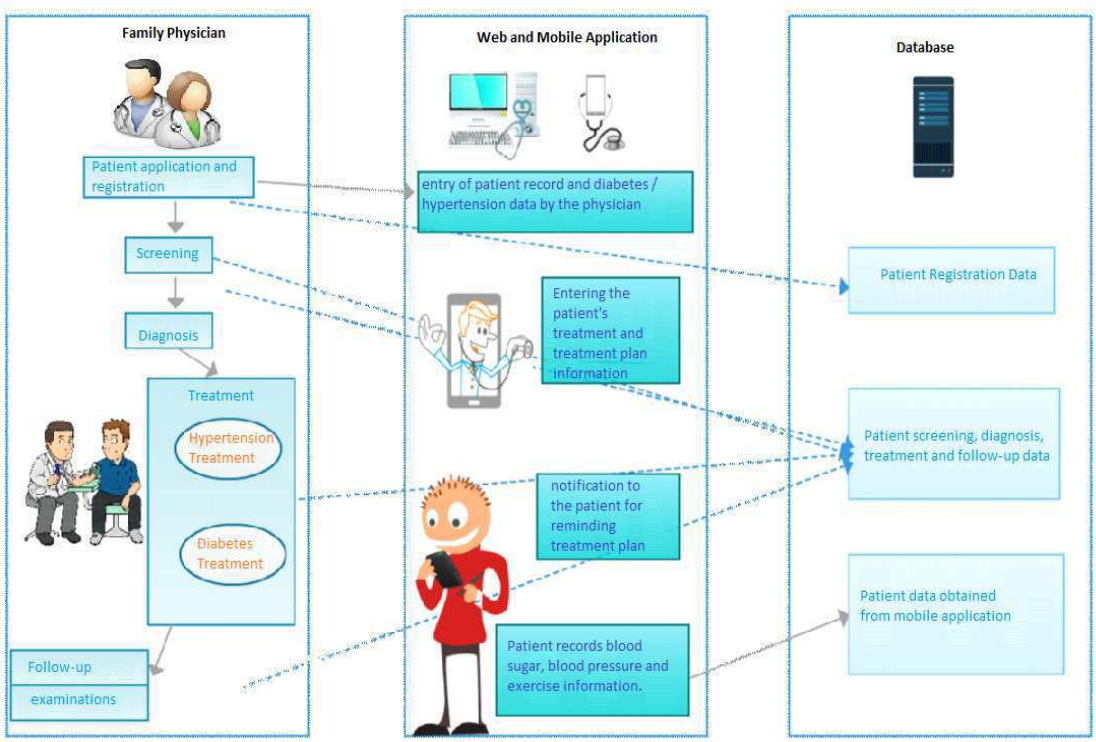


Figure 4.1 Overall system diagram

A registration is needed for physicians to access the system. If registered before, she/he logs in to the system with ID and password. Then, she/he searches the patient with ID number. If the patient has already been registered in system, the physician accesses the patient data, else new patient record is created.

Once the physician has accessed the general data of patient, she/he can check the diabetes, hypertension or periodic care system. According to the patient's main complaint, she performs screening, diagnosis, treatment and follow-up steps for diabetes or hypertension. The rule based clinical decision support system suggests a decision for each step according to the patient data obtained from the physician. In monitoring section, patient's self-measured values in the follow-up period are monitored. The rule based clinical decision support system is developed separately for each step such as screening, diagnosis, treatment and follow-up.

In machine learning based clinical decision support system, past collected patient data helps to make prediction about two different points. The first one is making prediction about blood glucose and /or blood pressure of the patient in the next ten days according to the past measured values. The second one is to predict hospitalization risk of any patient.

4.1 Database Design

The database management system used in this study is Microsoft SQL Server. 1B4T is abbreviation of Screening, Diagnose, Treatment and Monitoring in Primary care in Turkish: “1. Basamakta (1B) Tarama, Tanı , Tedavi ve Takip (4T)”. It is the name of the project as well. This abbreviation is located in front of the table names (Example: 1B4T _Diagnosis). The database design of web based system is given in Figure 4.2.

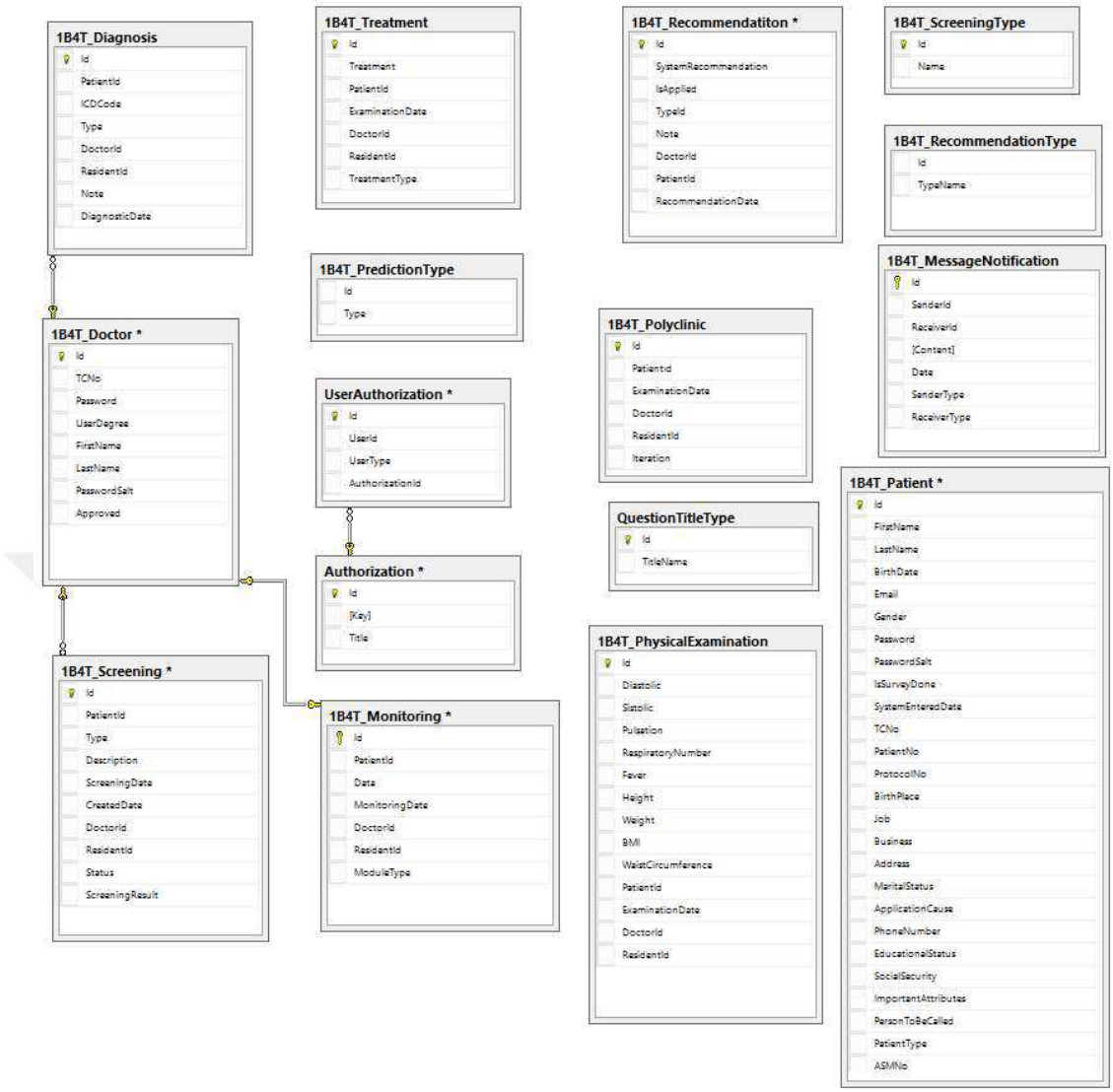


Figure 4.2 Database design of CDSMS

4.2 Web Application

The physicians register with the ID number and password. In main menu, main functions of the system are listed. They are; Patient Registration and Medical Examination, Policlinic Book, Appointment Book, Patient File, Diabetes Treatment, Hypertension Treatment and Messaging.

Patient registration is performed using the "Patient Registration and Medical Examination" tab. The physician takes the general information of the patient and saves it into the system. It is possible to switch to Diabetes and Hypertension

Treatment through this basic module or switch directly to Hypertension or Diabetes treatment through the main screen. A part of a new patient registration form is in Figure 4.3.

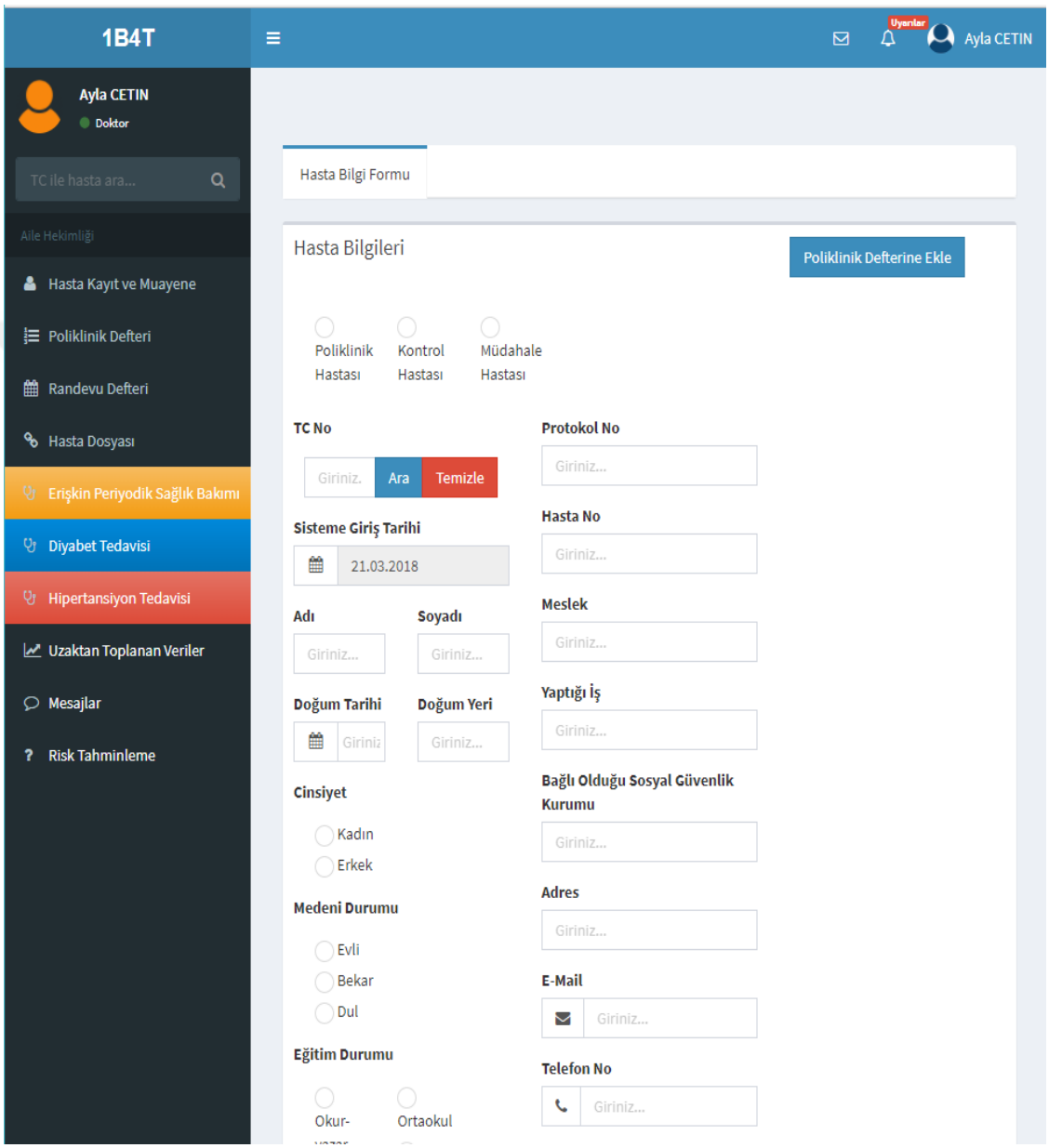


Figure 4.3 Patient registration form

In “Polyclinic Book” tab, patients coming in a selected date are searched and listed. Previous records of patients who visit the polyclinic in specified dates can be accessed. In “Appointments book” tab, daily, weekly and monthly appointments are presented to the physician as shown in Figure 4.4.

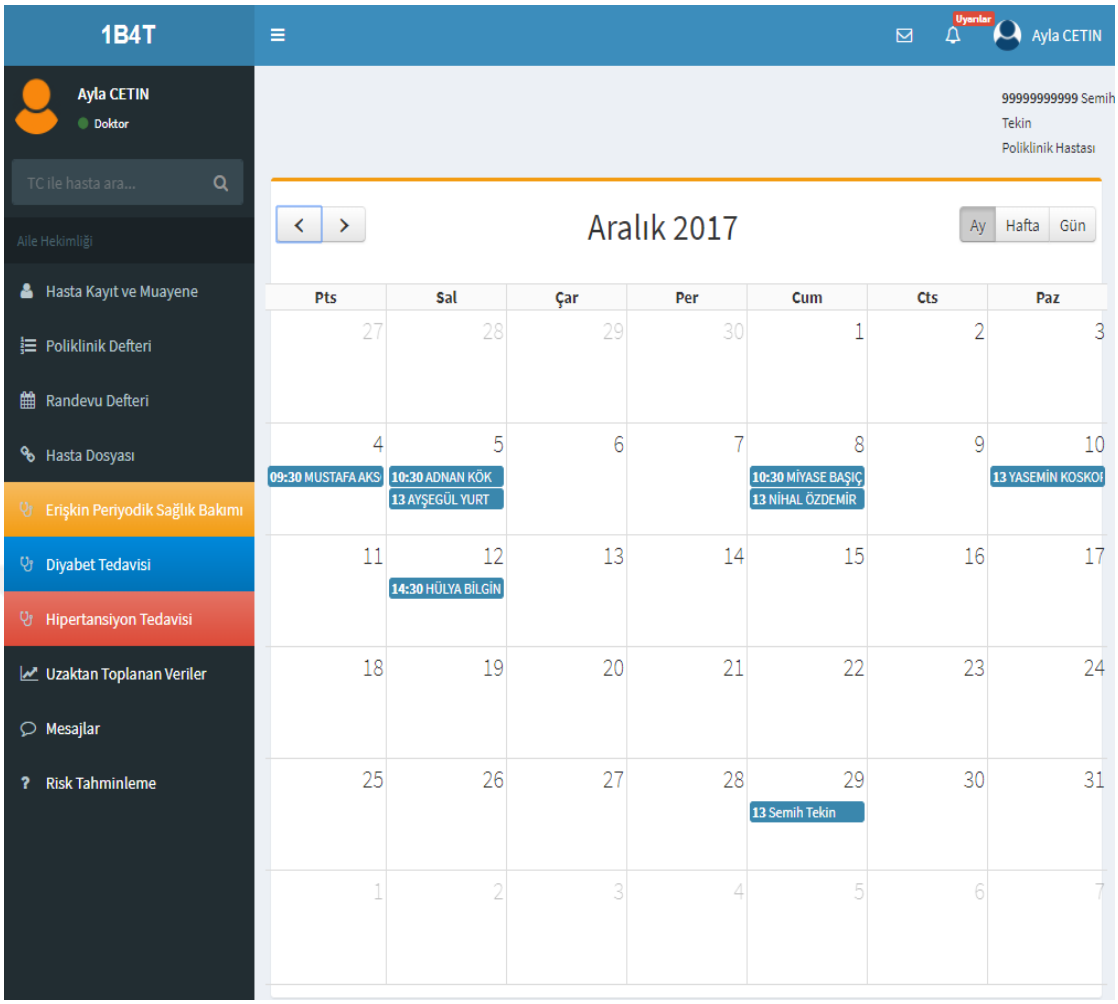


Figure 4.4 Appointments book

"Patient file" tab enables to show visit dates and other data of a certain patient by querying with patient ID no. Figure 4.5 is an example of a patient file.

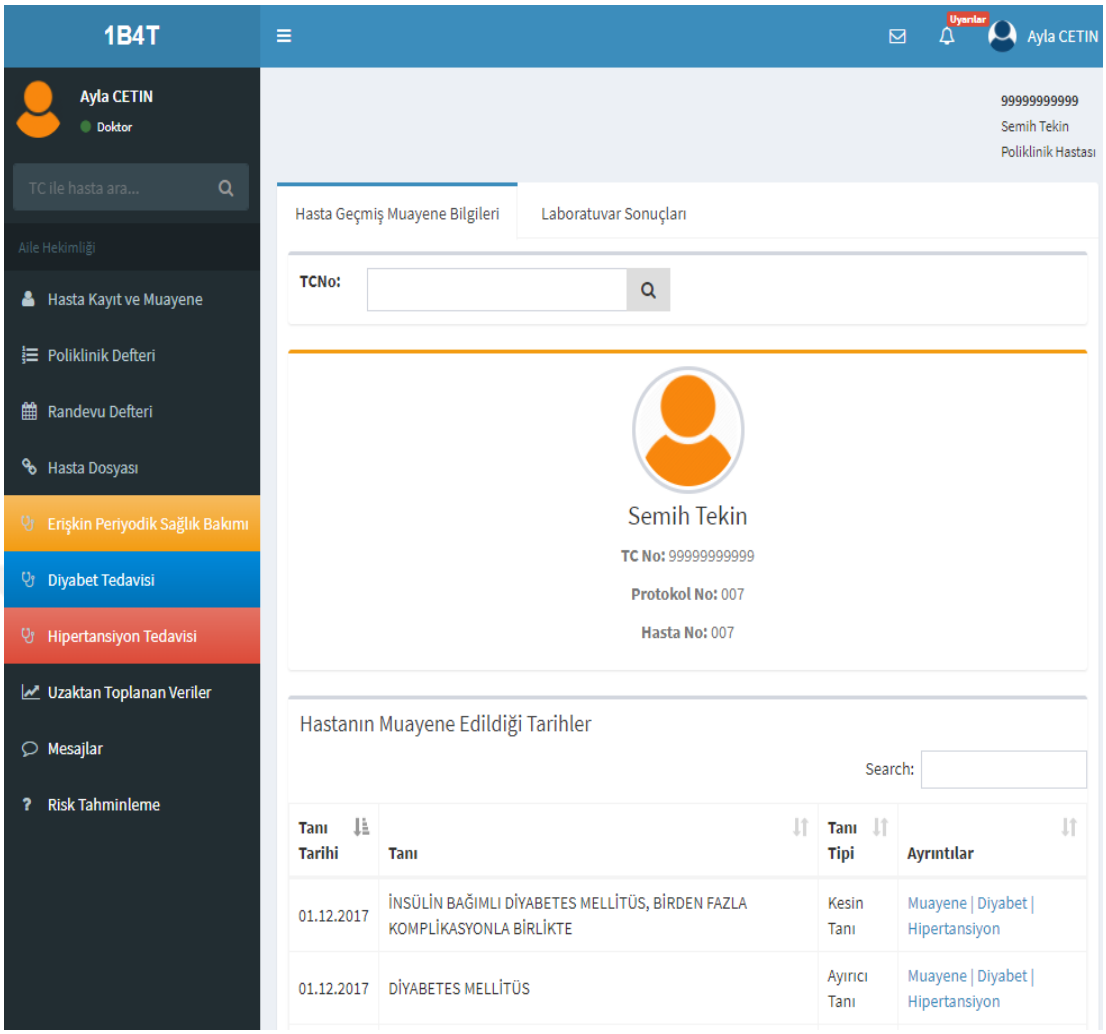


Figure 4.5 Patient file

4.2.1 Diabetes Module

When the physician selects the Diabetes Module, a screen is shown in which the physician can enter and save a patient's past medical history, current health status, family history, results of applied tests, physical examinations and laboratory results.

It is compulsory that History of the Current Disease, Past Medical History, Current Health Status, and Family History fields are filled in sequence, respectively. Patient scales do not have to be filled. Figure 4.6 is a screen of History of the current disease.

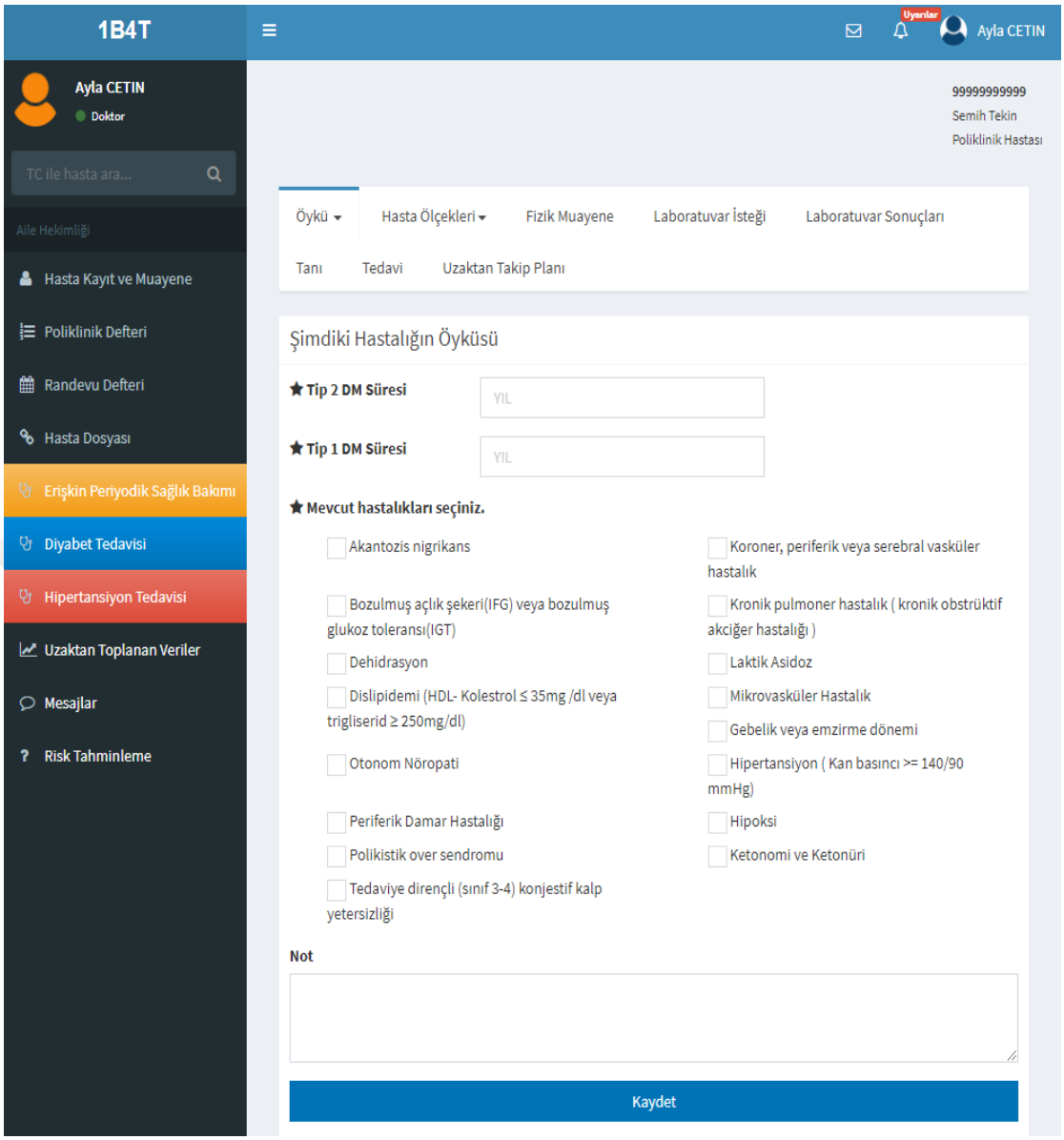


Figure 4.6 Diabetes - medical history of the current disease

It is also compulsory to fill the fields in the "Physical Examination" which is the next tab. Blood pressure, fever, waist circumference, weight, height, respiratory rate, pulse and some other parameters are entered to the system from this tab as shown in Figure 4.7.

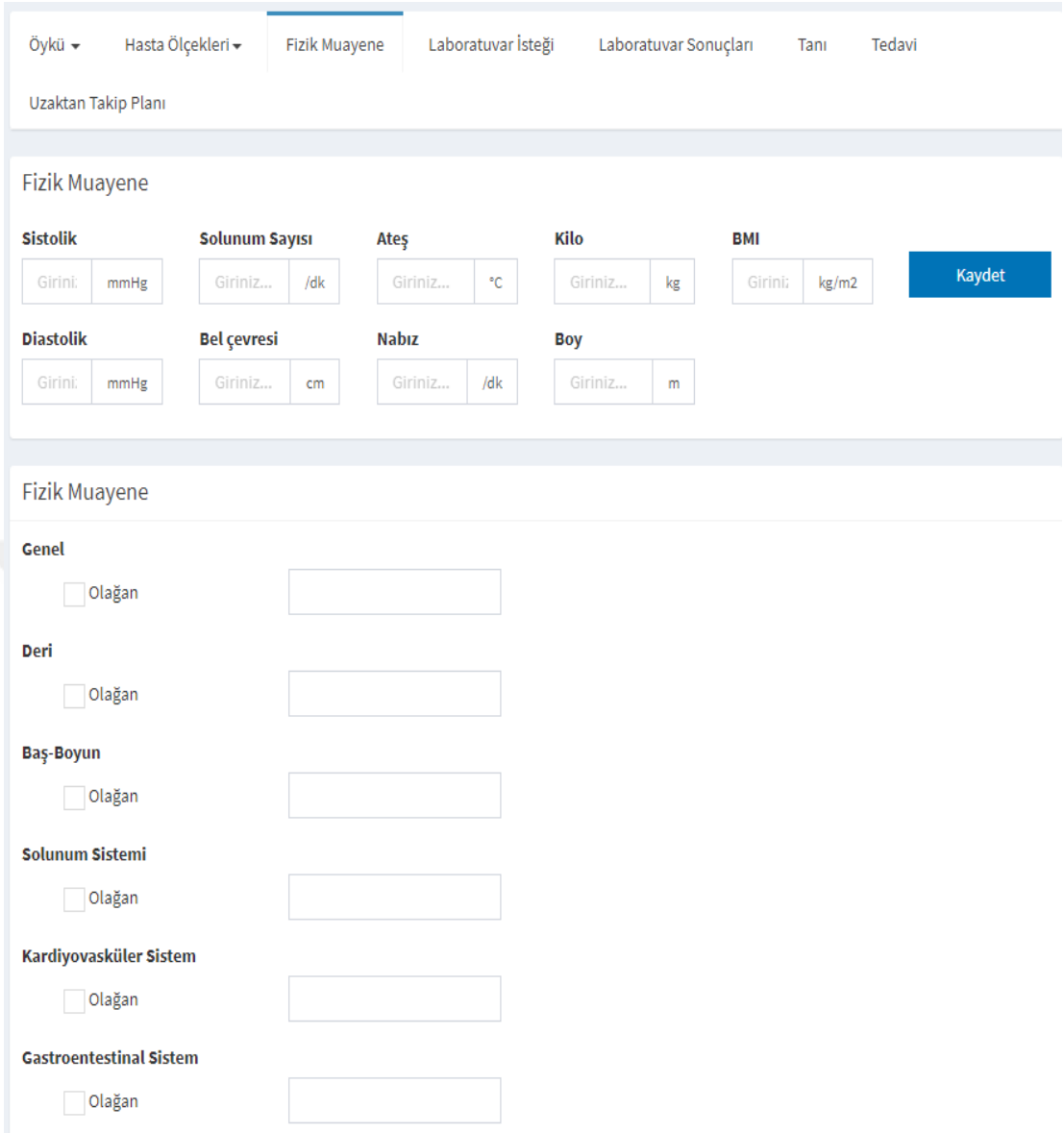


Figure 4.7 Diabetes - physical examination

When necessary fields are completed, a screening suggestion is presented to the physician. The suggestion may be “request fasting blood glucose measurement of patient now”, “screen the patient once a year” or “screen the patient every three years”. If she/he is to apply the suggestion by physician, it is ticked and saved as shown in Figure 4.8. The physician may apply these suggestions, or she may perform a treatment other than these suggestions. If she/he decides to apply a suggestion, she tickes and saves the suggestion. Otherwise she/he does not tick the suggestion and types her decision into the text field. This process is the same for all screening, diagnosis and treatment steps of both diabetes and hypertension modules.

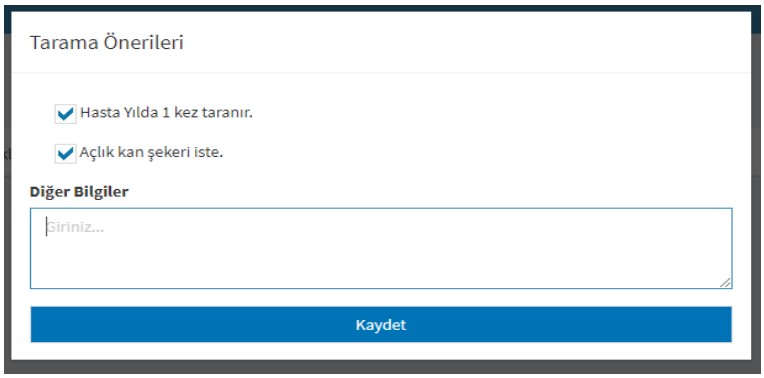


Figure 4.8 Diabetes - screening suggestion

After screening step, Laboratory analysis request is done from the next tab. Thus, the screening step, which is the first one, is completed. The user is redirected to main page. Figure 4.9 is the representation of laboratory analysis request page.

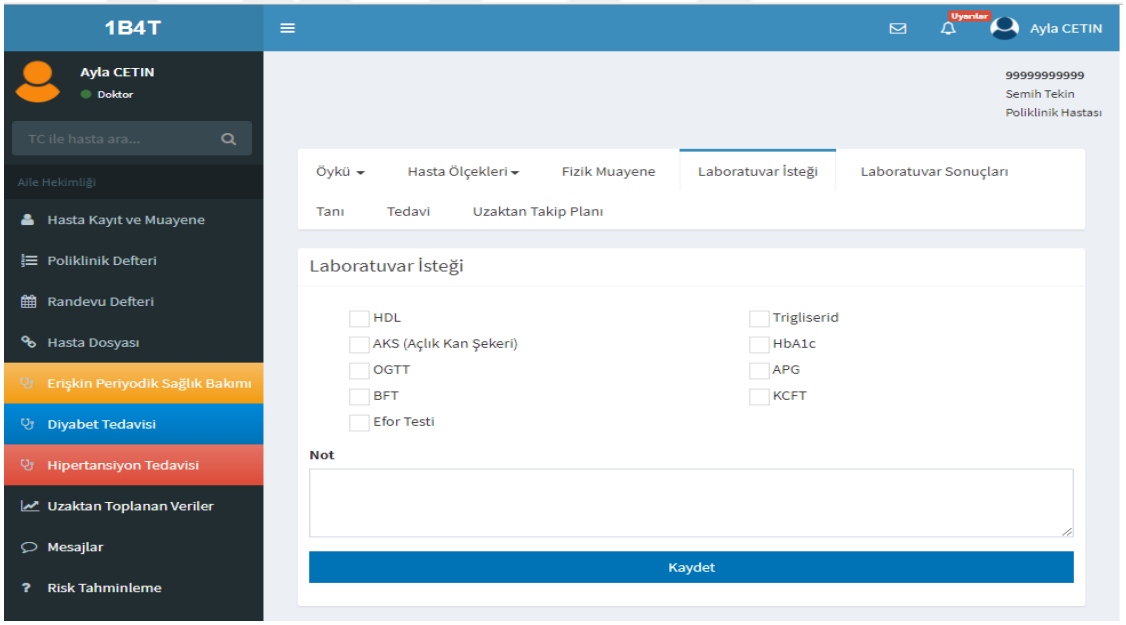


Figure 4.9 Diabetes - laboratory analysis request

The other step is diagnosis suggestions. It is also accessed from Diabetes Treatment Module. Laboratory analysis results are collected. As shown in Figure 4.10. The previous results of the patient are also listed in this page.

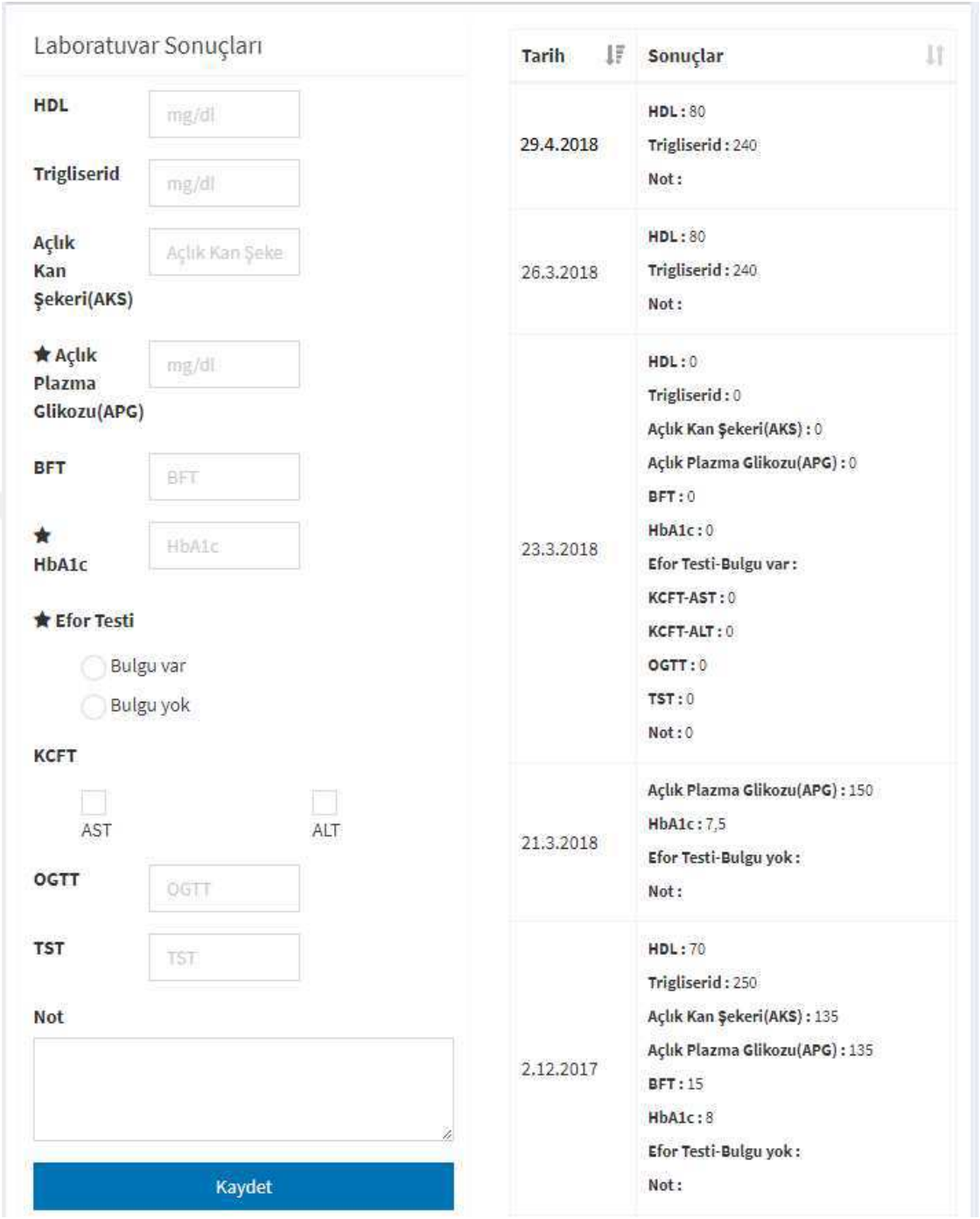


Figure 4.10 Diabetes - laboratory analysis results

According to the results of the laboratory analysis, a diagnosis is suggested to the physician. The diagnose suggestion may be “normal”, “prediabetes” or “diabetes”. If the diagnosis is diabetes, the page is redirected to Treatment page. In figure 4.11, diagnosis of the system is “diabetes”. The physician saves his/her own diagnose decision selecting from icd10 diagnoses list.

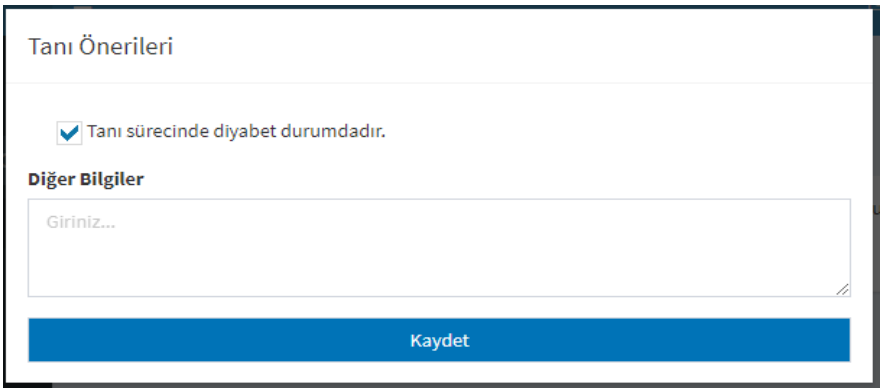


Figure 4.11 Diabetes - diagnosis suggestion

The next step is treatment suggestions. The treatment suggestions for the patient are presented at treatment tab. In Figure 4.12, a list of treatment suggestions are presented. The physician may apply these suggestions, or she/he may perform a treatment other than these suggestions.

The physician makes a patient-specific individualized treatment plan and schedules an appointment date with the patient. The appointment date is recorded to Appointment book. Then the patient goes through the follow-up phase.

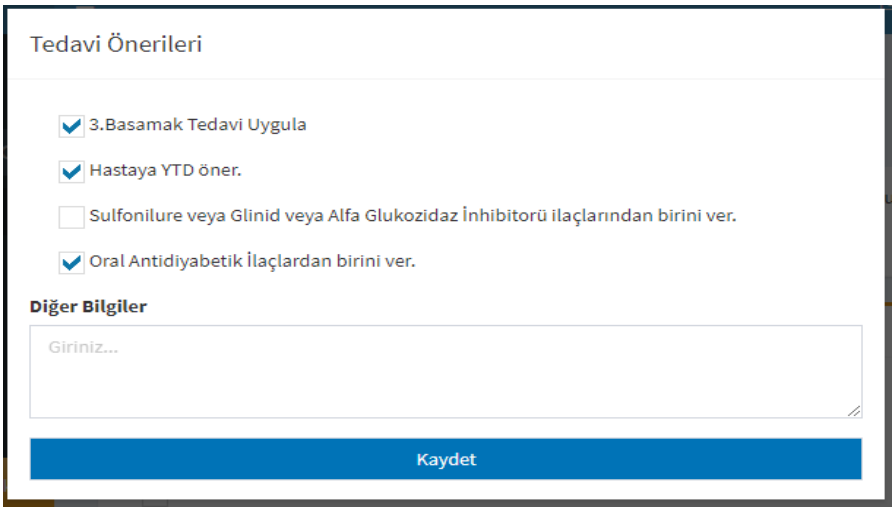


Figure 4.12 Diabetes - treatment suggestion

4.2.2 Hypertension Module

In the Hypertension Module, a screen is shown in which the physician can enter and save a patient's past medical history, current health status, family history, results of applied tests, physical examinations and laboratory results.

It is compulsory that History of the Current Disease, Current Health Status, and the Family History fields are filled in sequence, respectively. Patient scales do not have to be filled. Figure 4.13 is the interface of history of the current disease.

It is also compulsory to fill the fields in the "Physical Examination" which is the next tab. Blood pressure, fever, waist circumference, weight, height, respiratory rate, pulse and some other parameters are entered to the system from this tab. This part is common for both diabetes and hypertension modules.

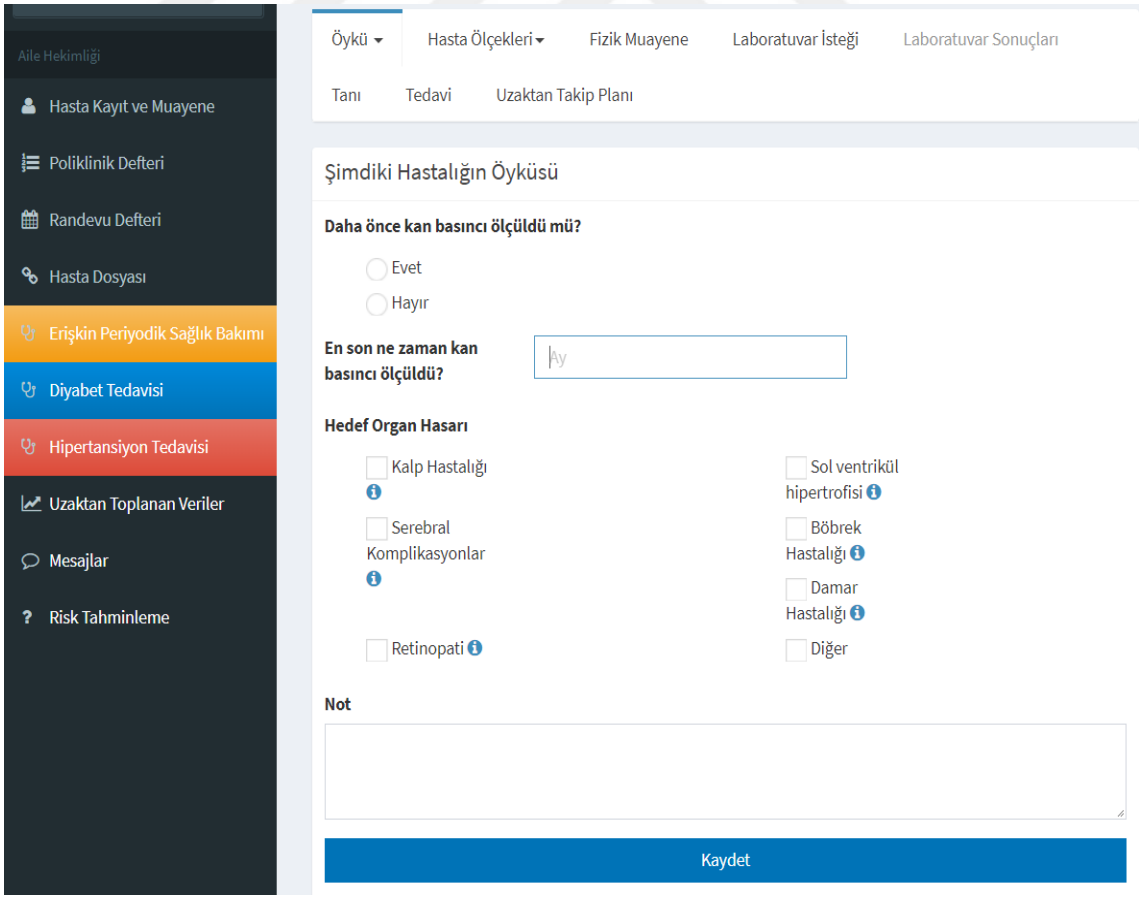


Figure 4.13 Hypertension - history of the current disease

Laboratory analysis request is done from the next tab. Figure 4.14 is the representation of laboratory analysis request page. Some values of patients such as fasting plasma glucose, HbA1c, cholesterol, uric acid, serum sodium, serum creatinine are requested from this page.

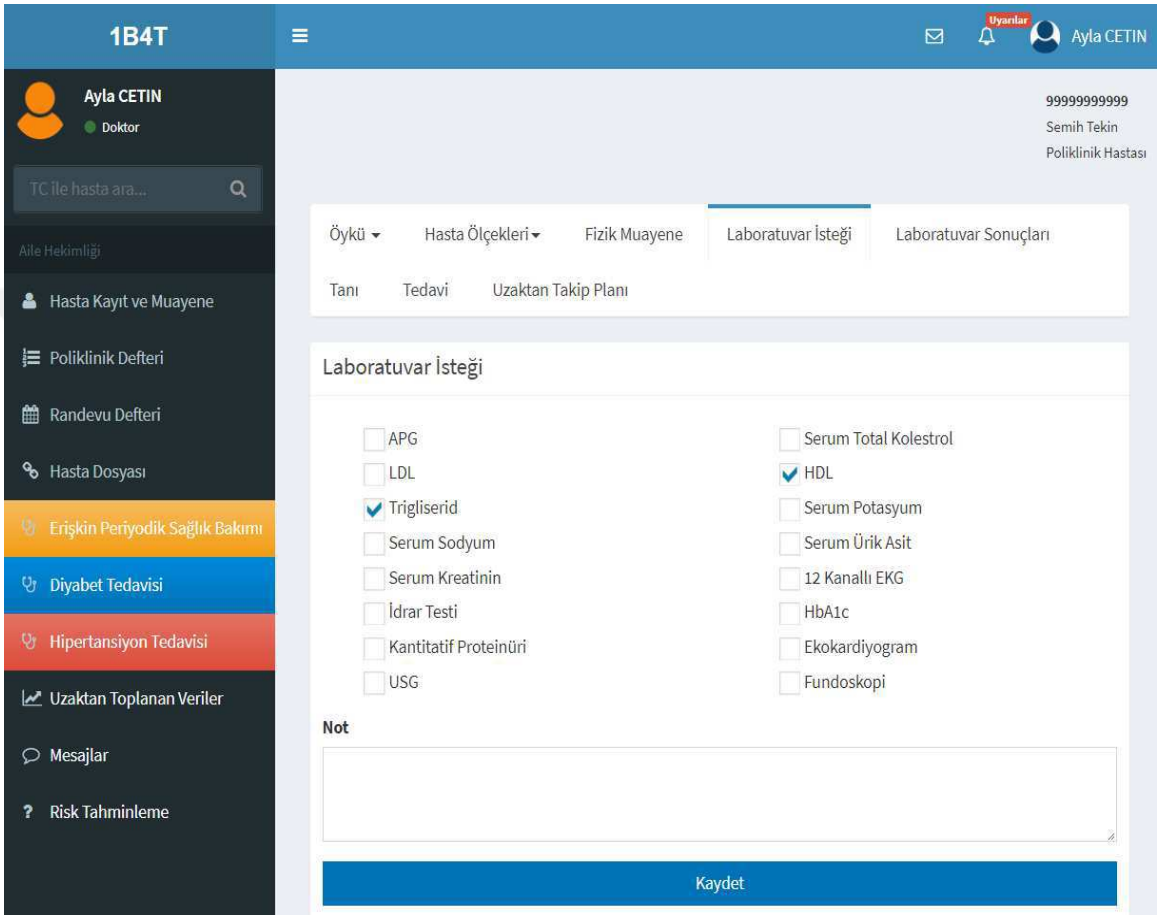


Figure 4.14 Hypertension - laboratory analysis request

Laboratory analysis results are collected. According to the results of the laboratory analysis, a diagnosis is suggested to the physician. The other step is diagnosis suggestions. When necessary fields are completed, a diagnosis suggestion is presented to the physician. The diagnose suggestion may be “optimal blood pressure”, “normal blood pressure”, “high-normal blood pressure”, “phase 1 hypertension”, “phase 2 hypertension” or “phase 3 hypertension”. If the diagnosis is hypertension, the page is redirected to Treatment page. In figure 4.15, diagnosis of the system is “phase 3 hypertension”.

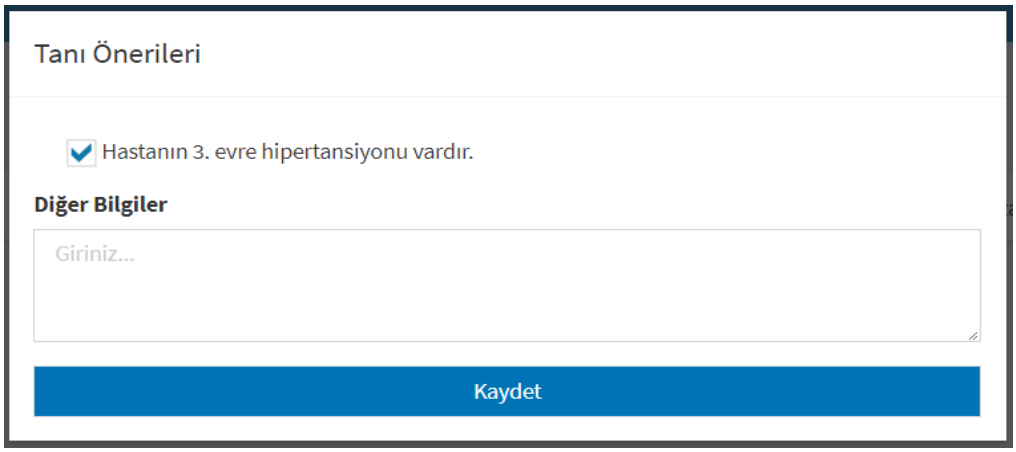


Figure 4.15 Hypertension - diagnosis suggestion

The physician saves his/her own diagnose decision selecting from icd10 diagnoses list. Diagnose type is also recorded to the system as shown in Figure 4.16.

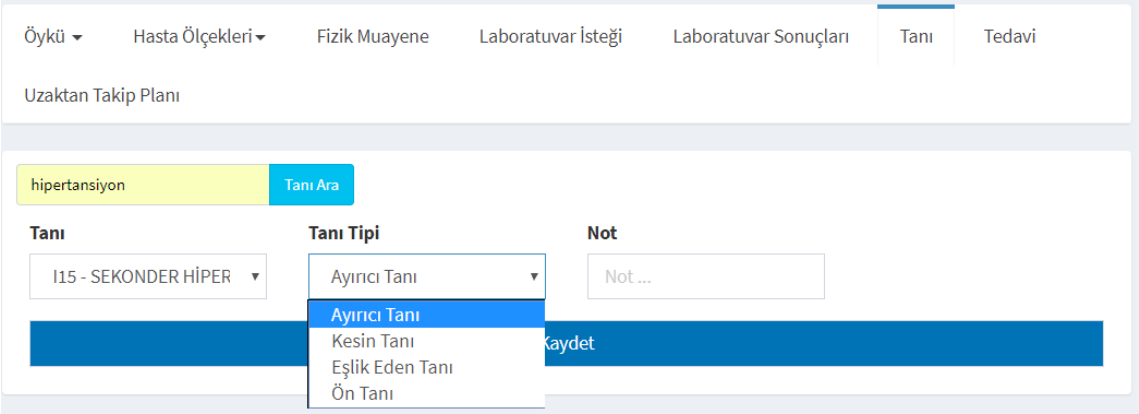


Figure 4.16 Hypertension – saving the diagnosis decision

The next step is treatment suggestions. The treatment suggestions for the patient are presented at “Treatment” tab. In Figure 4.17, a list of treatment suggestions are presented. In this figure, the treatment suggestions are lifestyle change and immediate medicine therapy. The physician makes a patient-specific individualized treatment plan and schedules an appointment date with the patient. The appointment date is recorded to Appointment book. Then the patient goes through the follow-up phase.

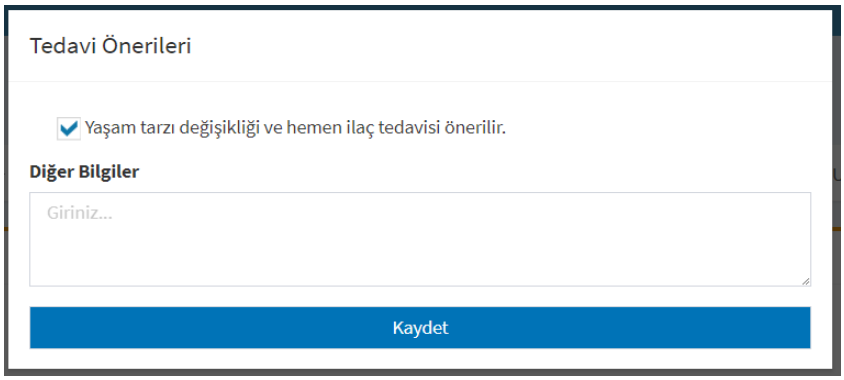


Figure 4.17 Hypertension - treatment suggestion

4.2.3 Remote Monitoring Plan

This part is common for both diabetes and hypertension modules. The android user patients must load the mobile health application into their mobile devices and sign up to the system. In “remote monitoring plan” tab, past monitoring plans of patients are listed. New plan can be defined as shown in Figure 4.18. The end date of the new plan is determined. New plan is forwarded to the patient's phone as a notification. The plan is reminded to the user at determined periods by notifications. Finally, examination process of the patient is completed.

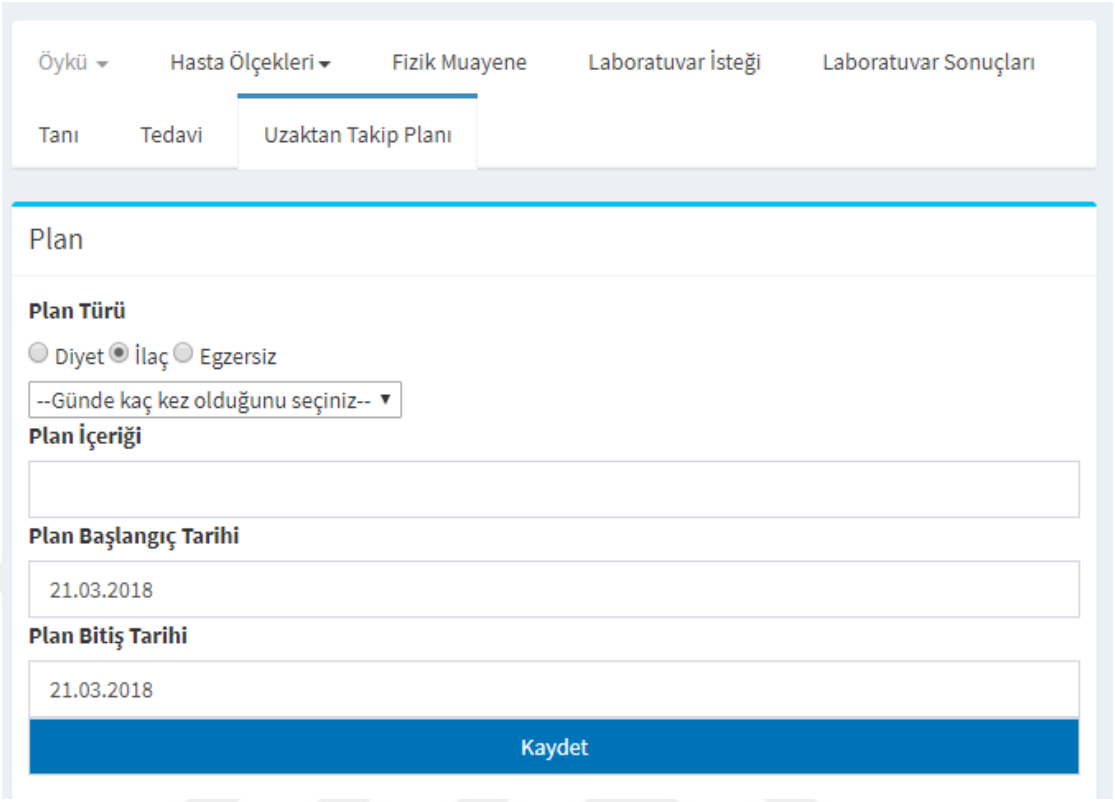


Figure 4.18 Remote monitoring plan

An instant messaging menu is also available on the main screen. This menu enables physicians to see previous messages from their patients and send new messages to their patients as shown in Figure 4.19.

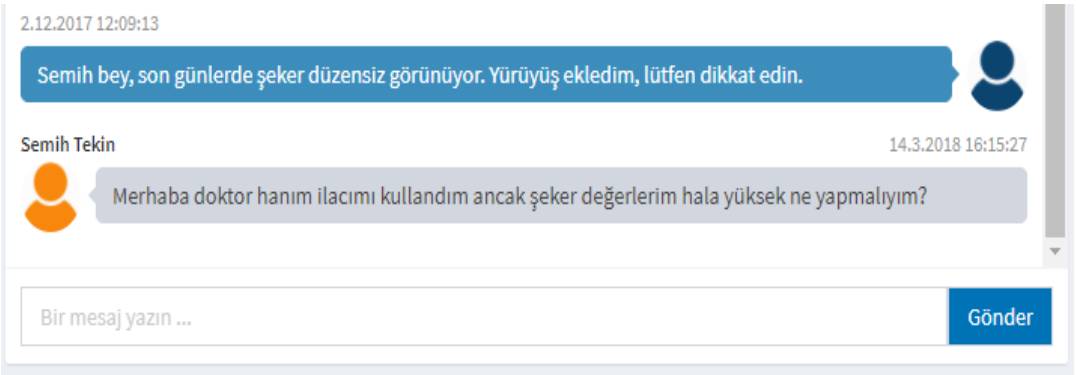


Figure 4.19 Instant messaging

The physician can monitor her/his patients' values remotely from the system. "Remotely Collected Data" section of the system shows related patient's data (blood glucose and blood pressure values) which the patient has entered to the mobile health

application at the periods determined by the physician. Thus, the physician can monitor remotely her/his patient's health status and if necessary, can change the appointment date to an earlier date. Remotely collected data of a patient is shown in Figure 4.20. In the other tabs of the interface, blood pressure and exercise data is also presented in the same way.

In this section, physician can also view the predicted values in next ten days. This prediction is based on time series analysis which is detailed in machine learning based clinical decision support system section of the thesis.

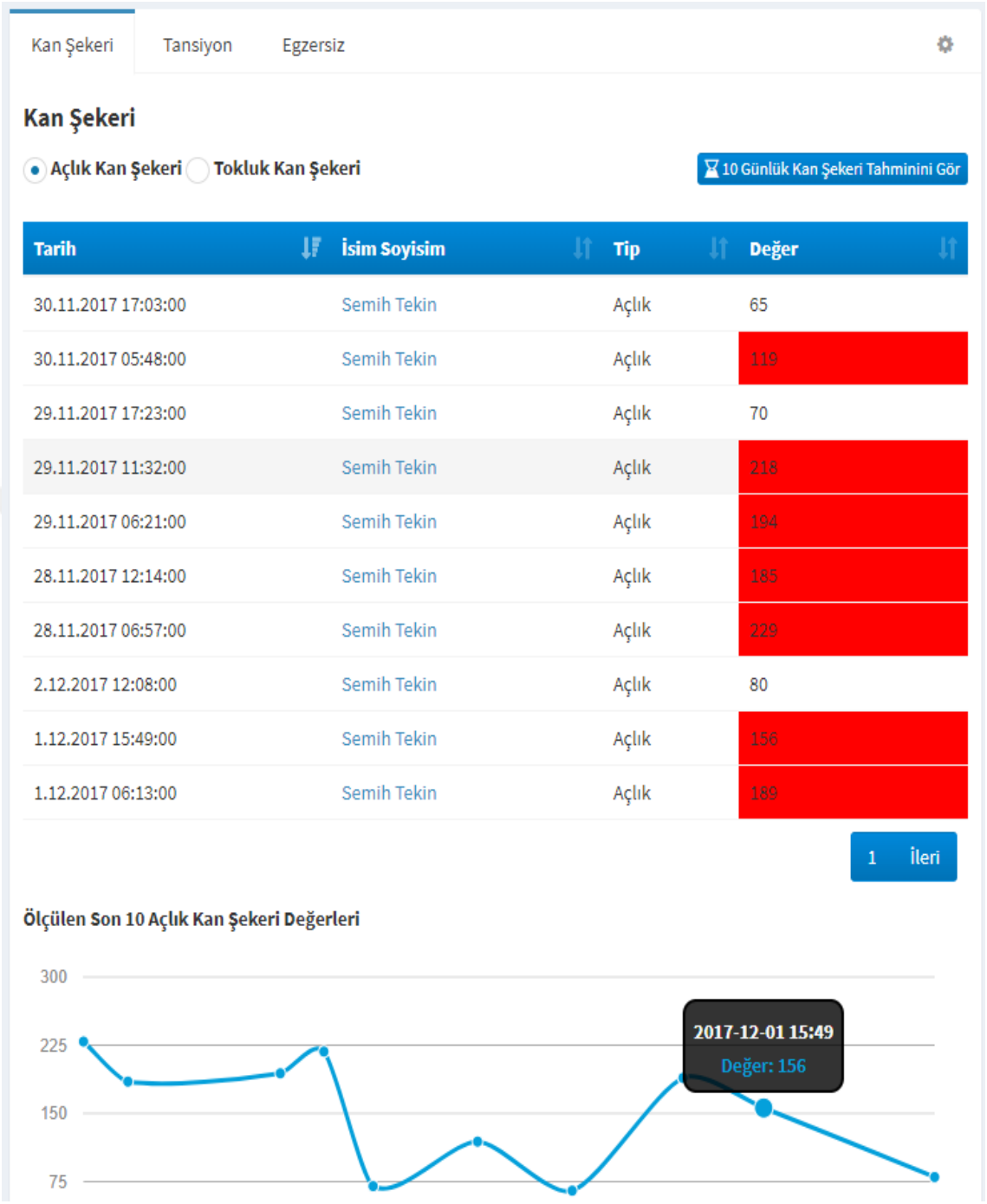


Figure 4.20 Remotely collected data

4.3 Rule Based Clinical Decision Support System

The rule based clinical decision support system has been developed based on the rules obtained from evidence-based guidelines (American Diabetes Association, 2015). The web based system provides screening, diagnosis and treatment suggestions to primary care physicians. It has been developed separately for each step such as screening, diagnosis, treatment and follow-up, and suggests a decision for each step according to the patient data gathered by the physician.

The rules of clinical decision support system have been built by family medicine physicians. They built these rules using evidence-based guidelines and drew flow charts for each screening, diagnosis, treatment and follow-up steps. They used a software tool for drawing these flowcharts. The flowcharts constituted the common language between the developers and physicians. These flowcharts were converted into xml files by developers and they are parsed automatically by the software.

In the next sections of this chapter, flowcharts of the decision rules for diabetes are presented.

4.3.1 Diabetes Decision Support System

4.3.1.1 Diabetes Screening Rules

In diabetes screening system; gender, age, height, weight, BMI (Body Mass Index), waist circumference, blood pressure, HDL cholesterol and triglyceride values are examined and the patient is diagnosed or it is decided to rescan the patient at which interval. Diagnostic steps are performed after the patient is diagnosed with diabetes. Diabetes screening rules are shown in Figure 4.21.

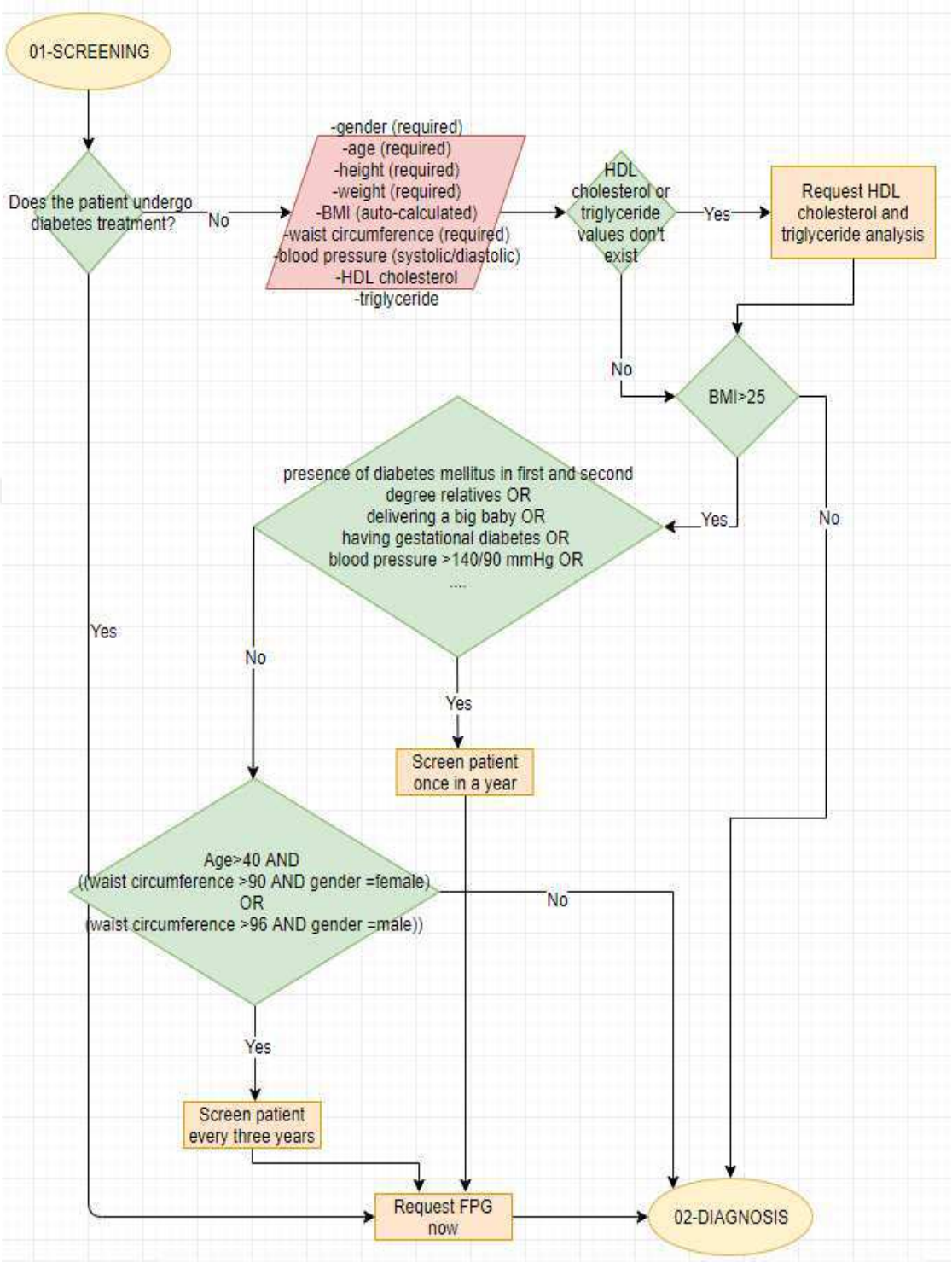


Figure 4.21 Diabetes screening flowchart

4.3.1.2 Diabetes Diagnosis Rules

In diabetes diagnosis system; FPG or A1C, and 75 g glucose OGTT values are examined to determine whether the patient is normal, prediabetes, or needs diabetes treatment process. Diabetes diagnosis flowchart is presented in Figure 4.22.

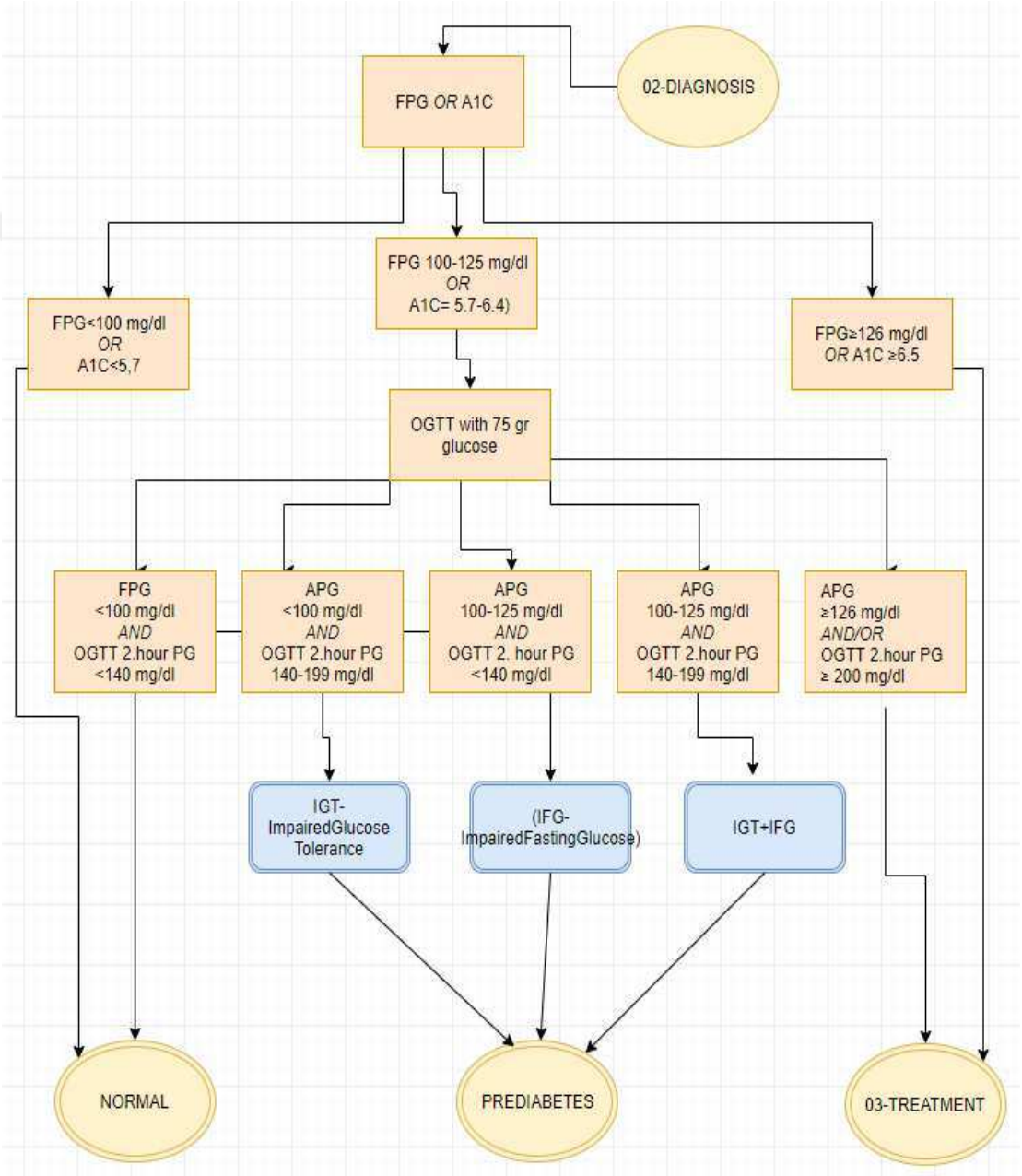


Figure 4.22 Diabetes diagnosis flowchart

4.3.1.3 Diabetes Treatment Rules

The purpose of the diabetes treatment system is; to determine the diabetes treatment stage of the patient and to initiate treatment accordingly. The patient's "HbA1C" value is examined to determine the diabetes treatment stage. The patient is treated according to this stage. In general flowchart (Figure 4.23), treatment stage of the patient is decided.

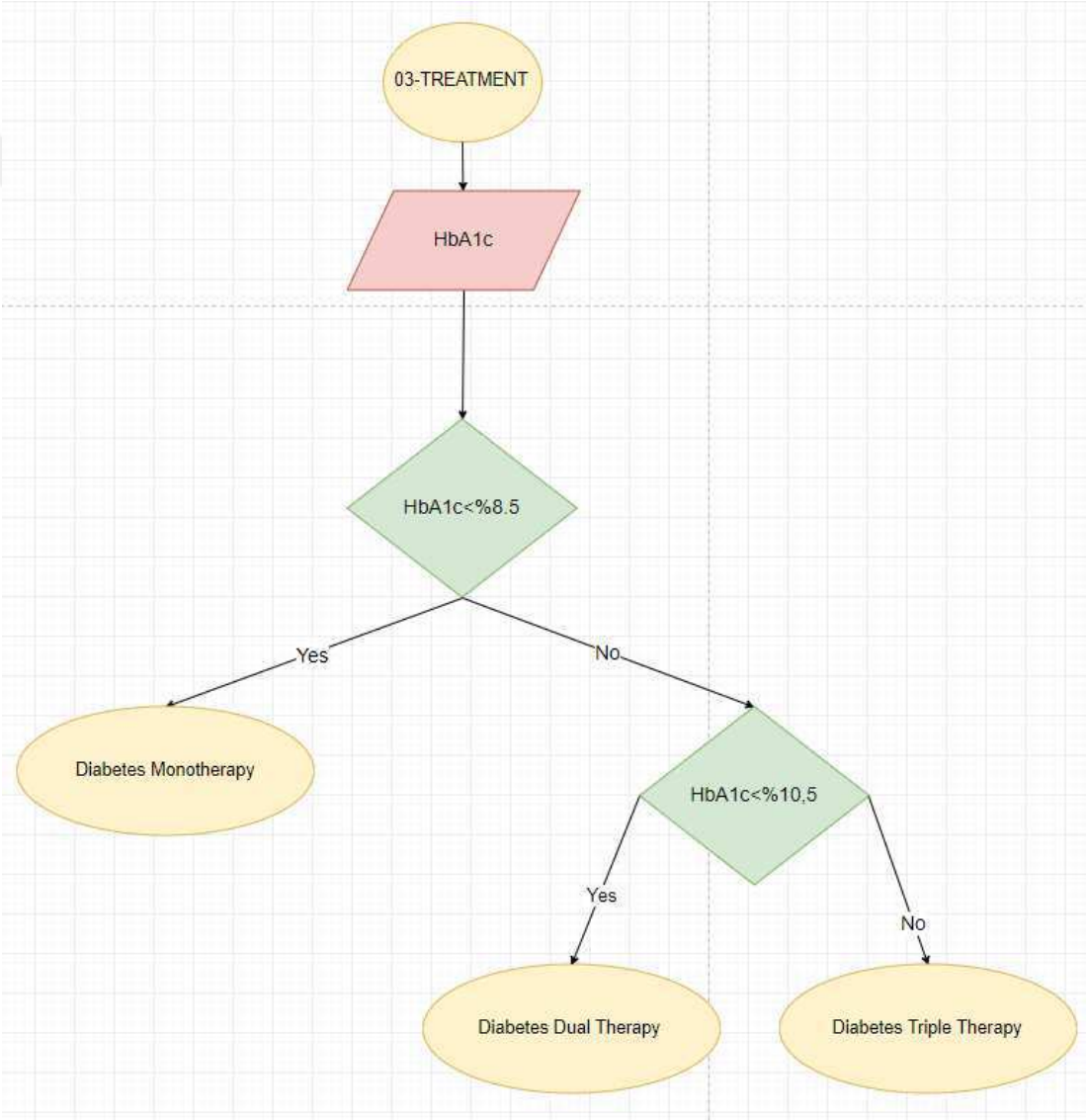


Figure 4.23 Diabetes treatment - general flowchart

4.3.1.3.1 Diabetes Monotherapy. Diabetes monotherapy decision rules are detailed in Figure 4.24.

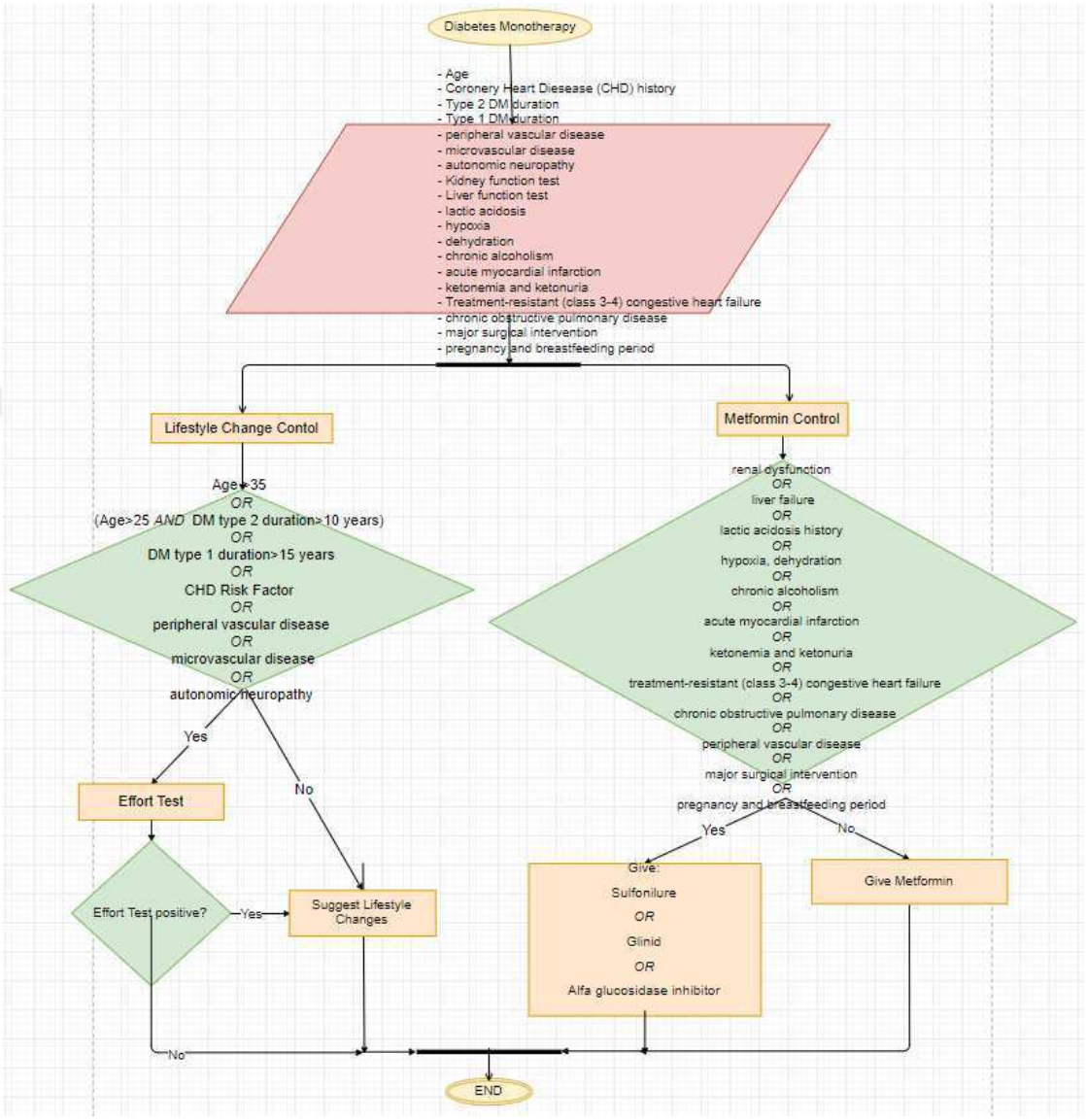


Figure 4.24 Diabetes monotherapy flowchart

4.3.1.3.2 Diabetes Dual Therapy. Diabetes dual therapy rules are detailed in Figure 4.25.

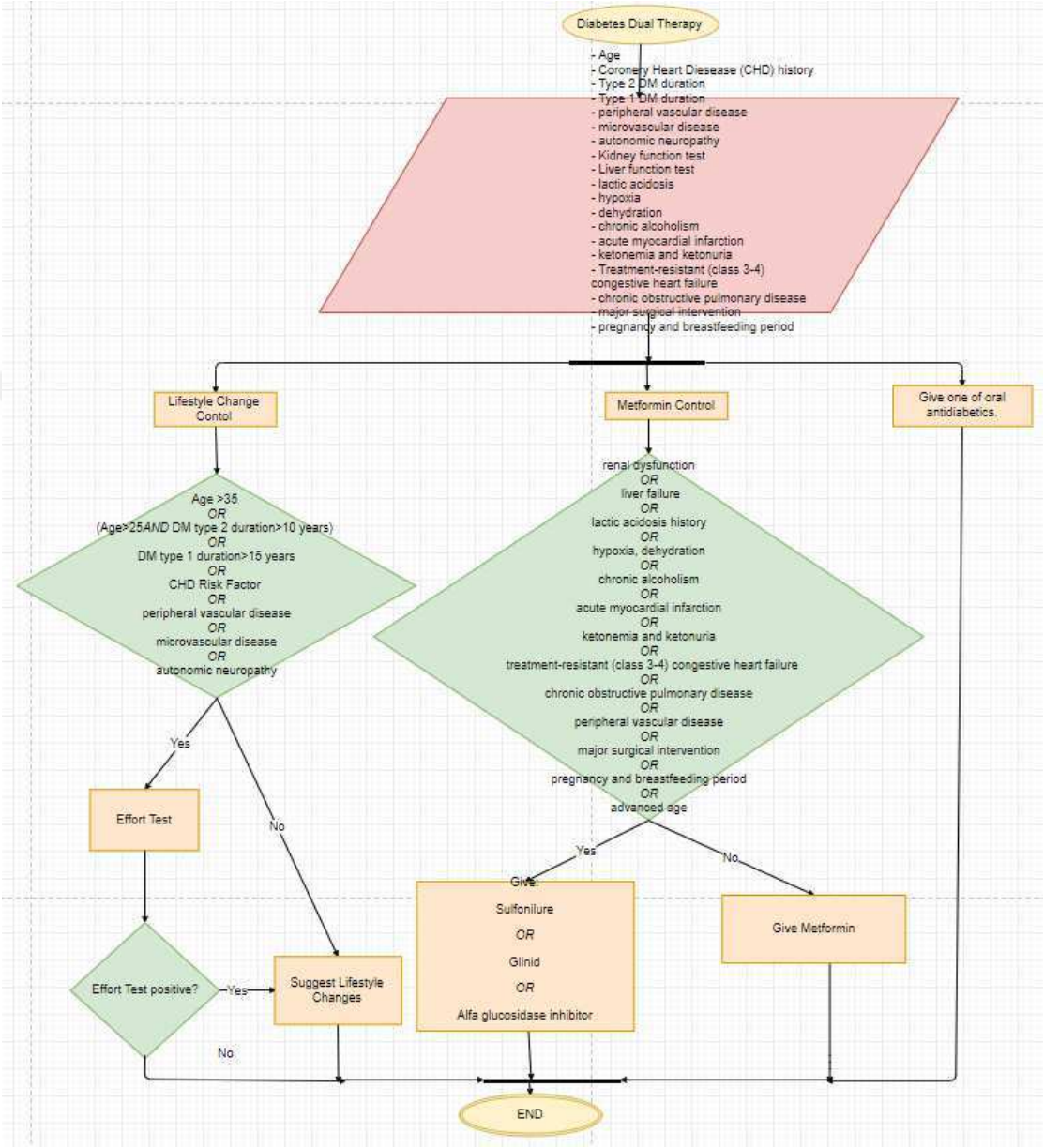


Figure 4.25 Diabetes dual therapy flowchart

4.3.1.3.3 Diabetes Triple Therapy. Diabetes triple therapy decision rules are detailed in Figure 4.26.

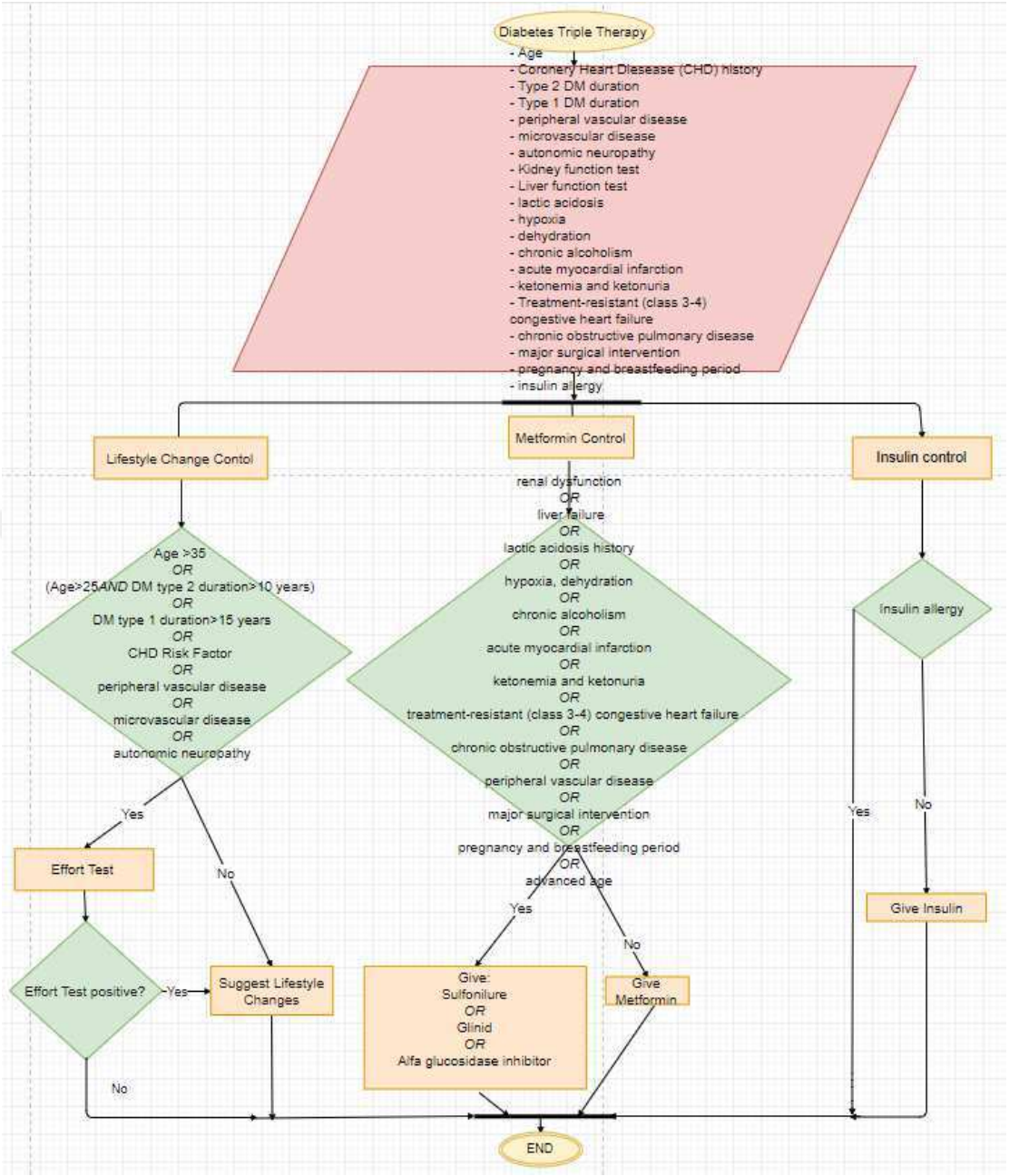


Figure 4.26 Diabetes triple therapy flowchart

In diabetes treatment system; age, coronery heart disease (CHD) history, type 2 diabetes duration, type 1 diabetes duration, peripheral vascular disease, microvascular disease, autonomic neuropathy, kidney function test, liver function test, lactic acidosis, hypoxia, dehydration, chronic alcoholism, acute myocardial infarction, ketonemia and ketonuria, treatment resistant congestive heart failure, chronic obstructive pulmonary disease, major surgical intervention, pregnancy and

breastfeeding period are examined and treatment process is started. The patient's parameters detailed above are evaluated in terms of lifestyle changes and medication.

4.3.1.4 Diabetes Follow-up Rules

In follow-up system, follow-up process is specified considering the stage of treatment and evaluating the HbA1C value of the patient. The flowchart of follow-up system is detailed in Figure 4.27.

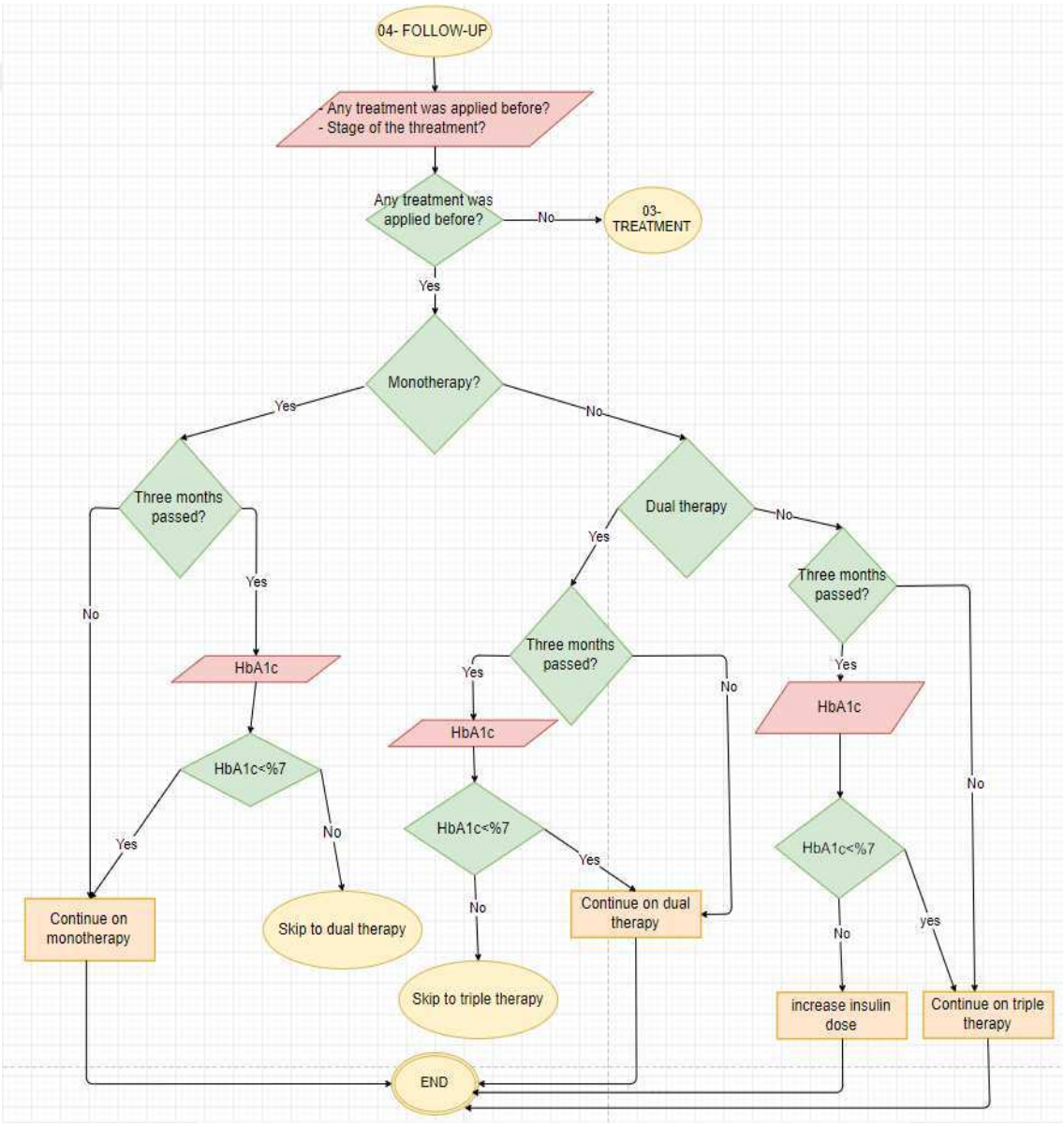


Figure 4.27 Diabetes follow-up flowchart

4.3.2. Hypertension Decision Support System

4.3.2.1 Hypertension Screening Rules

In hypertension screening system; age, BMI (Body Mass Index) and TA (Tension Arterial) measurement value are taken. Hypertension screening rules are shown in Figure 4.28.

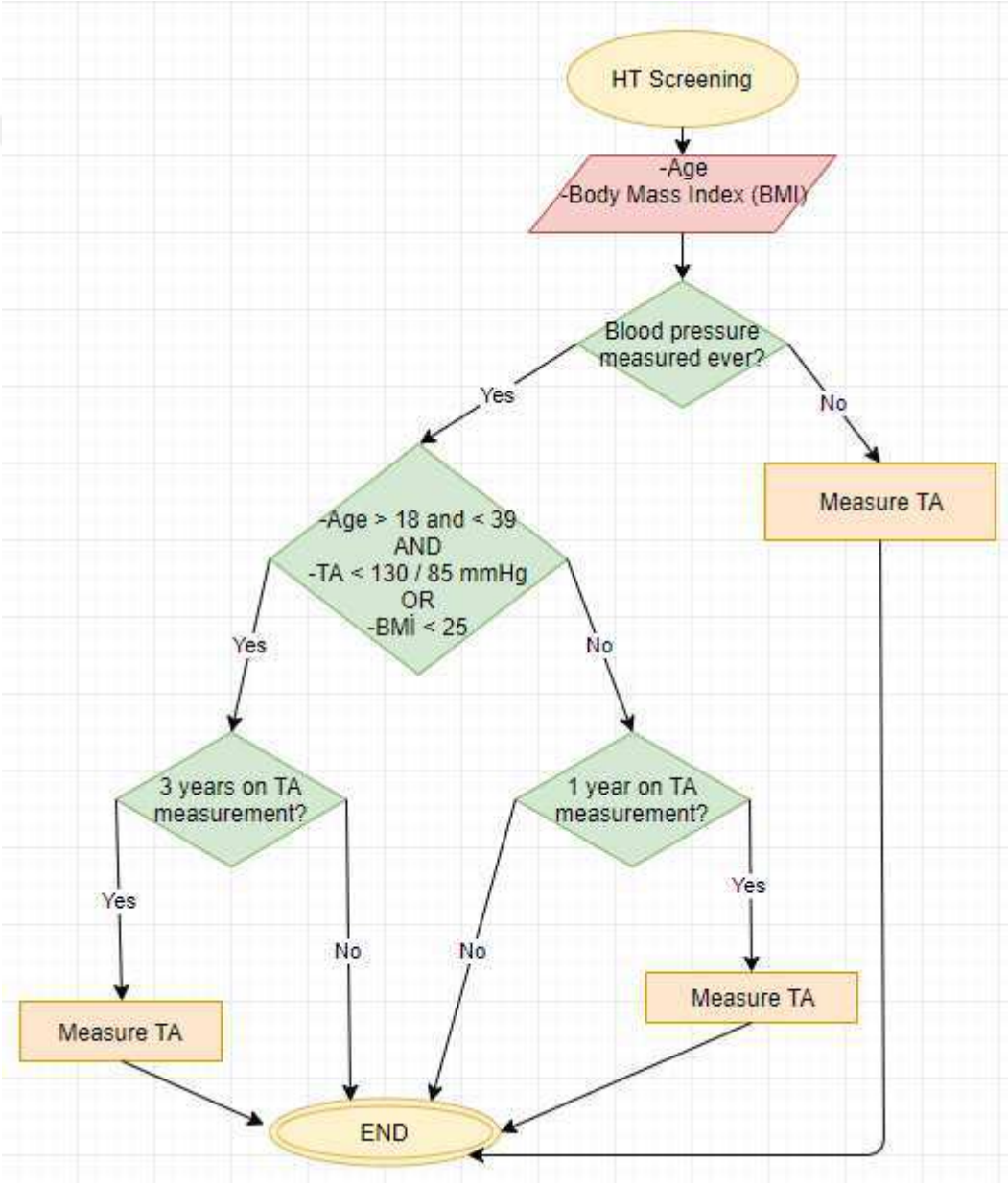


Figure 4.28 Hypertension screening flowchart

4.3.2.2 Hypertension Diagnosis Rules

In hypertension diagnosis system; Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) values are examined to determine whether the patient has optimal, normal, high-normal blood pressure or hypertension phase 1, phase 2 or phase 3. Hypertension diagnosis flowchart is presented in Figure 4.29.

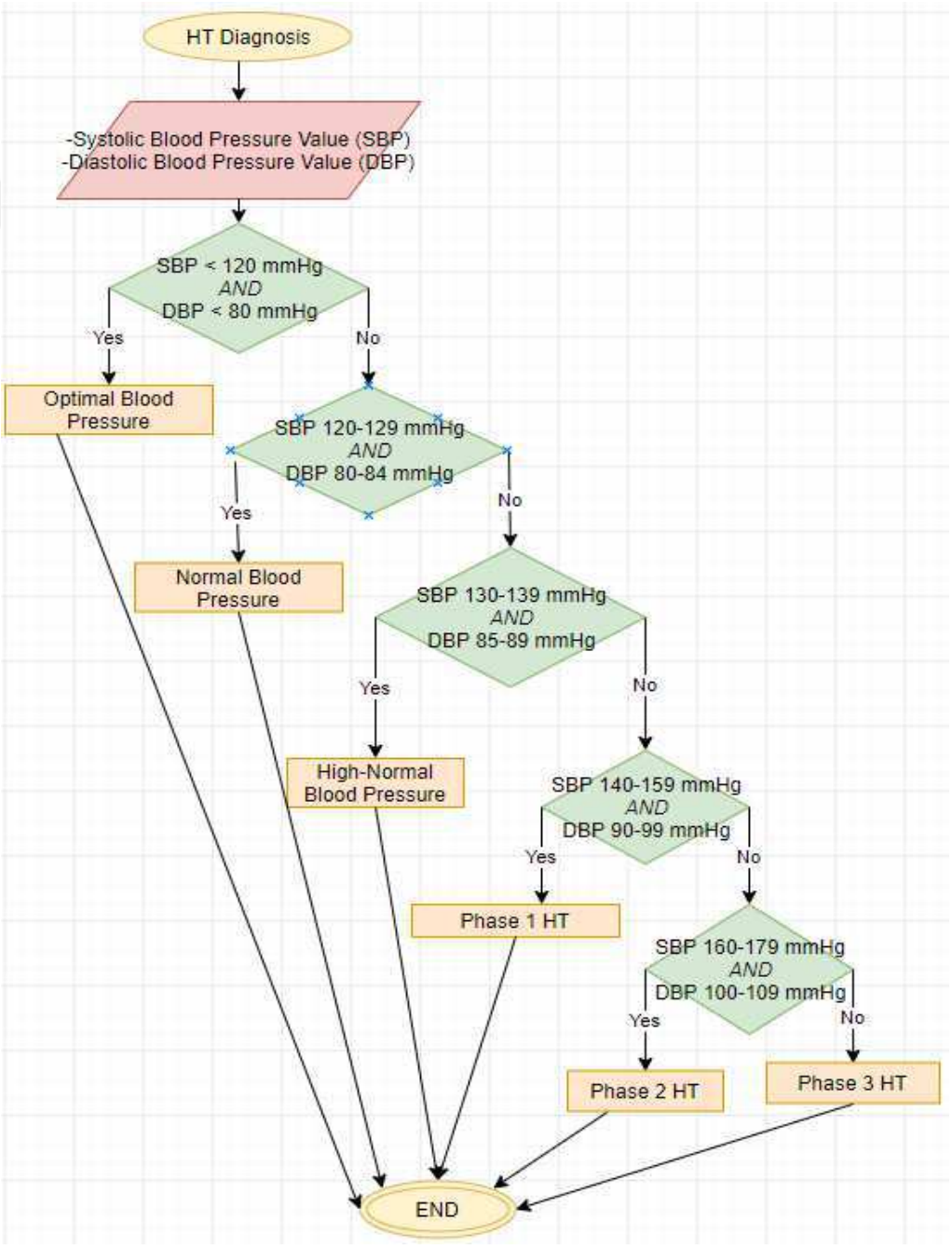


Figure 4.29 Hypertension diagnosis flowchart

4.3.2.2 Hypertension Treatment Rules

Hypertension treatment decision rules are detailed in Figure 4.30. These rules determine the risk level of patient. Appropriate treatment is applied according to these risk levels. The treatment options for the each risk level are listed below:

-Low Risk: Lifestyle changes for several months are applied. If blood pressure cannot be controlled, medication should be applied.

-Moderate Risk: Lifestyle changes for several weeks are applied. If blood pressure cannot be controlled, medication should be applied.

-High Risk: Lifestyle changes + Medication are applied.

-Very High Risk: Lifestyle changes + immediate medication treatment is applied.

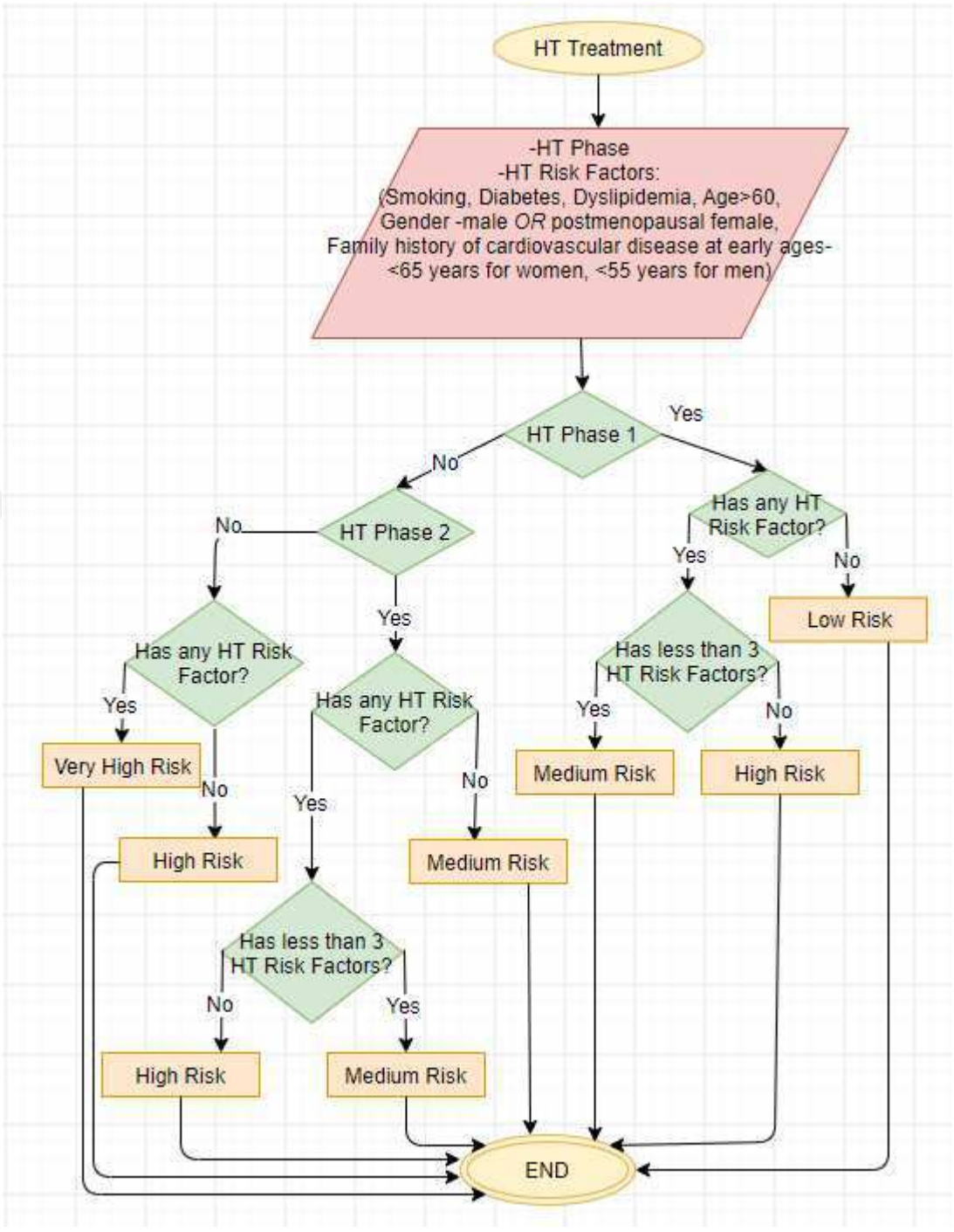


Figure 4.30 Hypertension treatment flowchart

4.5 Machine Learning Based Clinical Decision Support System

4.5.1 Decision Tree Based Clinical Decision Support

In decision tree based clinical decision support system, data of past patients help to make prediction about hospitalization risk of a new patient. Gender, age, weight, amount of medication, fasting plasma glucose (FPG), HbA1c, amount of insulin used, and number of diagnoses are attributes of the constructed decision tree model. These attributes are taken from the physician using the following user interface in Figure 4.31. After filling the required fields, the physician clicks submission button and the prediction result is shown to the physician with a message such as “the patient has/ has not risk” below the screen in blue background near an exclamation point icon.

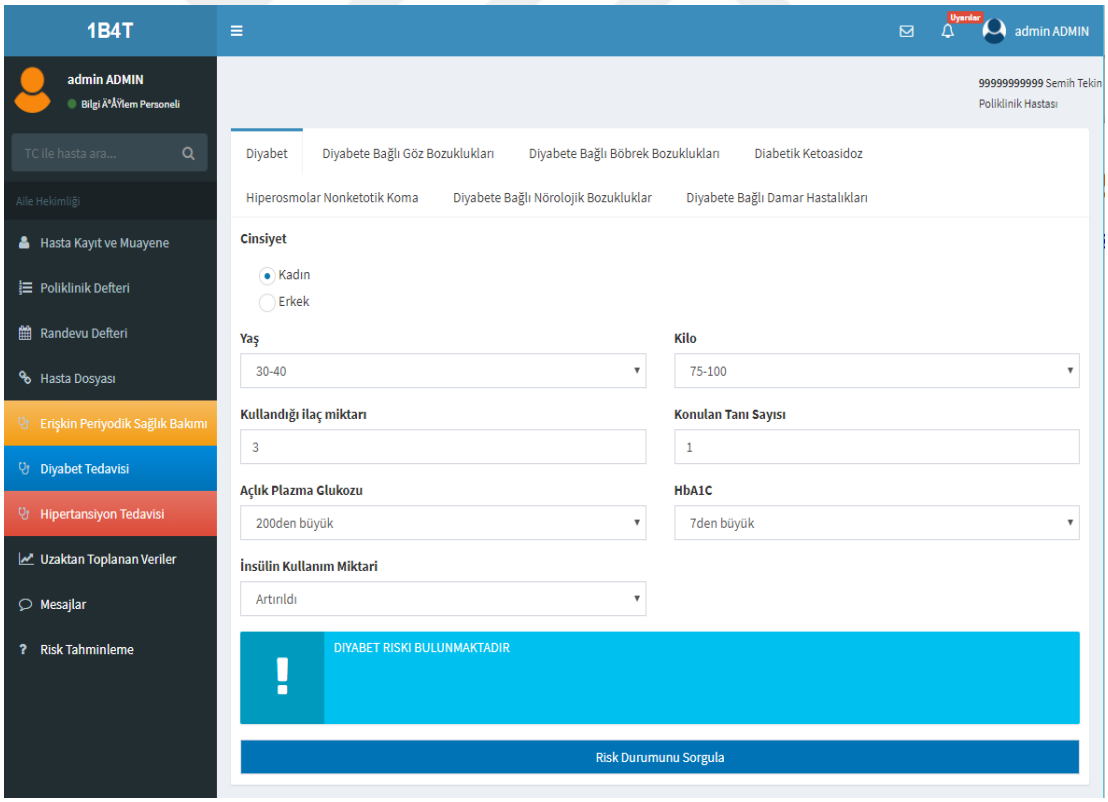


Figure 4.31 Prediction of a patient’s risk

The system is trained and tested with a public diabetes dataset (UCI Machine Learning Repository, 2010) because the system has just been developed and there is not yet enough patient data for constructing a data mining model. C4.5 decision tree algorithm (Mitchell, T. M., 1997) is used to predict a patient's risk. It is implemented in Weka as a classifier called J48.

Ten-fold cross validation was used for validation of the model. The average accuracy was found as 80.4%. The weighted average precision and recall are 0.796 and 0.804 respectively. ROC Area value is 0.88 which is a considerable value. ROC curve method is one of the methods used to determine the discrimination of the test in the medical decision-making process. If the positives are perfectly separated from the negatives, the AUC (ROC Curve) value is 1, and if no positive value is found, this value is 0. The larger this area, the more likely it is that the test has the ability to distinguish it. Other performance measures are also given below in Table 4.1.

Table 4.1 Detailed performance measures by class

	TP Rate	**FP Rate**	**Precision**	**Recall**	**F-Measure**	**ROC Area**	**Class**
	0.510	0.108	0.585	0.510	0.545	0.88	No
	0.892	0.490	0.859	0.892	0.875	0.88	Yes
Weighted Avg.	0.804	0.402	0.796	0.804	0.799	0.88	

4.5.2 Time Series Analysis Based Clinical Decision Support

Time series analysis was used to predict a patient's ten days blood glucose values. The developed mobile health application collects patients' blood glucose values. Patients input their blood glucose measurement values regularly into the daily program on the application in line with the given plan by their physician. The collected measurement values are used in time series analysis to predict the patient's blood glucose values in ten days. This prediction will give the physician an insight

into trend of the blood glucose value of the patient. Figure 4.32 shows the predicted fasting plasma glucose values of a sample patient for next the ten days.

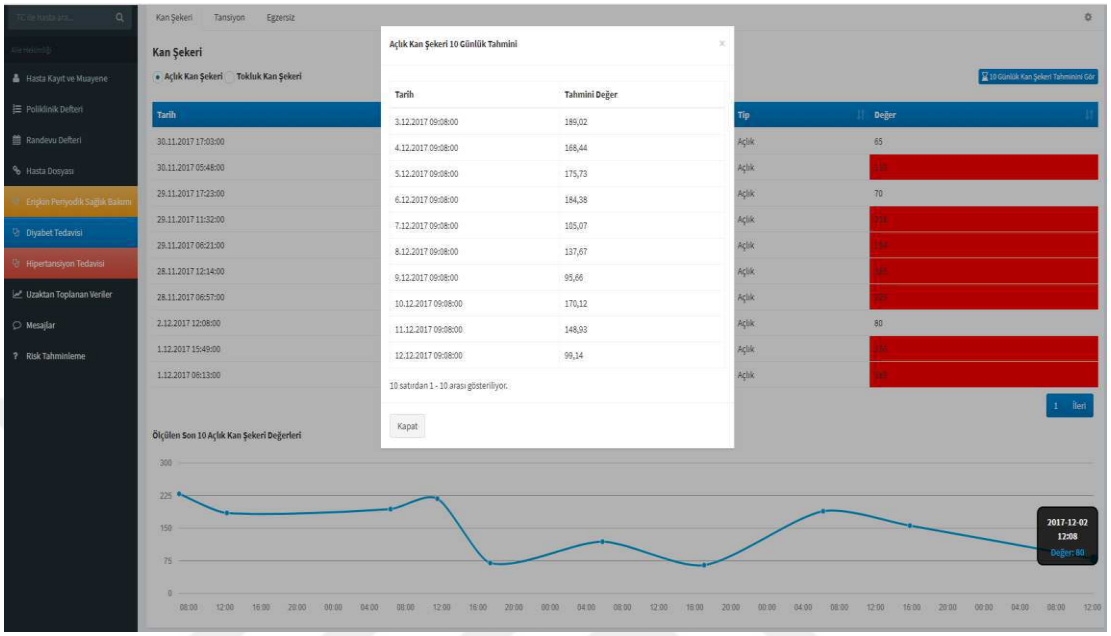


Figure 4.32 Prediction of a patient's fasting blood glucose for next ten days

Weka's time series framework adopts a machine learning approach to model time series by transforming the data into a form that can be manipulated by standardized predictive learning algorithms. This removes the temporal ordering of individual input samples by encoding the time dependency via additional input fields. These fields are sometimes called "lagged" variables. Other fields are automatically computed for modeling trends and seasonality. Once the data is transformed, any of regression algorithms of Weka can be applied to learn a model. In this study, multiple linear regression has been applied.

CHAPTER FIVE
MOBILE HEALTH APPLICATION

Mobile applications, which have been popular recently, have common and effective usage in medical field. These applications can help people to manage their health and access to useful information when and where they need it. According to industry estimates, 500 million smartphone users worldwide will be using a health care application by 2015, and by 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications.

For the purpose of easy health monitoring, hypertension and diabetes patients can save and display blood pressure, blood glucose measurement and walking exercise from the mobile application. Thus, these measurements of patients can be monitored by their family physicians. Also, patients can fill a survey that helps family physicians to detect symptoms of a disease.

The aim of the study is to create an application which helps users to have a healthy lifestyle by recording and analyzing their blood glucose, blood pressure measurements and walking exercises. Thus, patients can check and manage past measurements and exercise values, and these values can also be monitored by their own family physicians.

In this system, users must be log in to the application to manage their blood pressure, blood glucose measurements and walking exercises. There are also options for creating a new account or forgotten password in the login screen.

In order for the patient to be able to use mobile application, registration with a user name or email address is necessary. Patients fill a survey at once after the registration. In this survey, there are some questions like using cigarette, using alcohol, amount of using, breakfast time, etc. This information can be used for detecting symptoms of diseases. After filling the survey, system is directed to main screen in which blood pressure, blood glucose measurements and walking exercises

can be displayed, saved, updated or deleted. This enables to manage records easily. Notifications are sent to the patients at specified times according to their individual plans determined by their physicians and a feedback is received from the users. Patients are also able to communicate with the physician using the mobile application.

User profile can be displayed or updated. Also, last survey filled in by user can be edited from the menu icon. In fact, all surveys of users are stored in the database to analyze later. The work flow diagram of the mobile health application is shown in Figure 5.1.

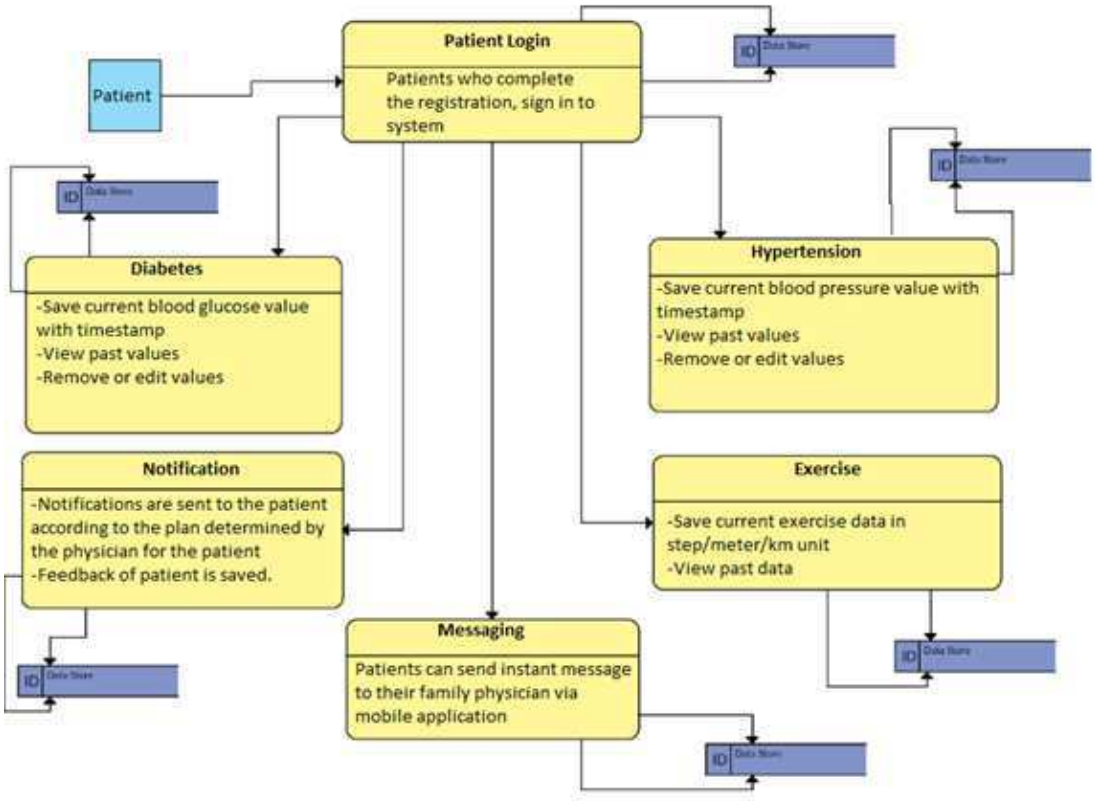


Figure 5.1 Mobile health application flowchart

5.1 Database Design

The database tables were created by considering system requirements. They store user data, measurements, survey answers and messages. Tables are interconnected by common attributes to ensure ownership and easy access to information. The database with the name of 1B4T was created. The database tables are shown in Figure 5.2.

These tables were used to store information about patient, blood pressure, blood glucose, walking exercise, survey, plan, message etc. Message notification table stores temporary data which is copy of entries which are inserted to message table and triggered after insert operation. This table is used for sending message notification to user. When controlling new messages of user, this table is searched and after sending notification, the related entry is deleted. The feedback table is used to store user's response to plan notification.

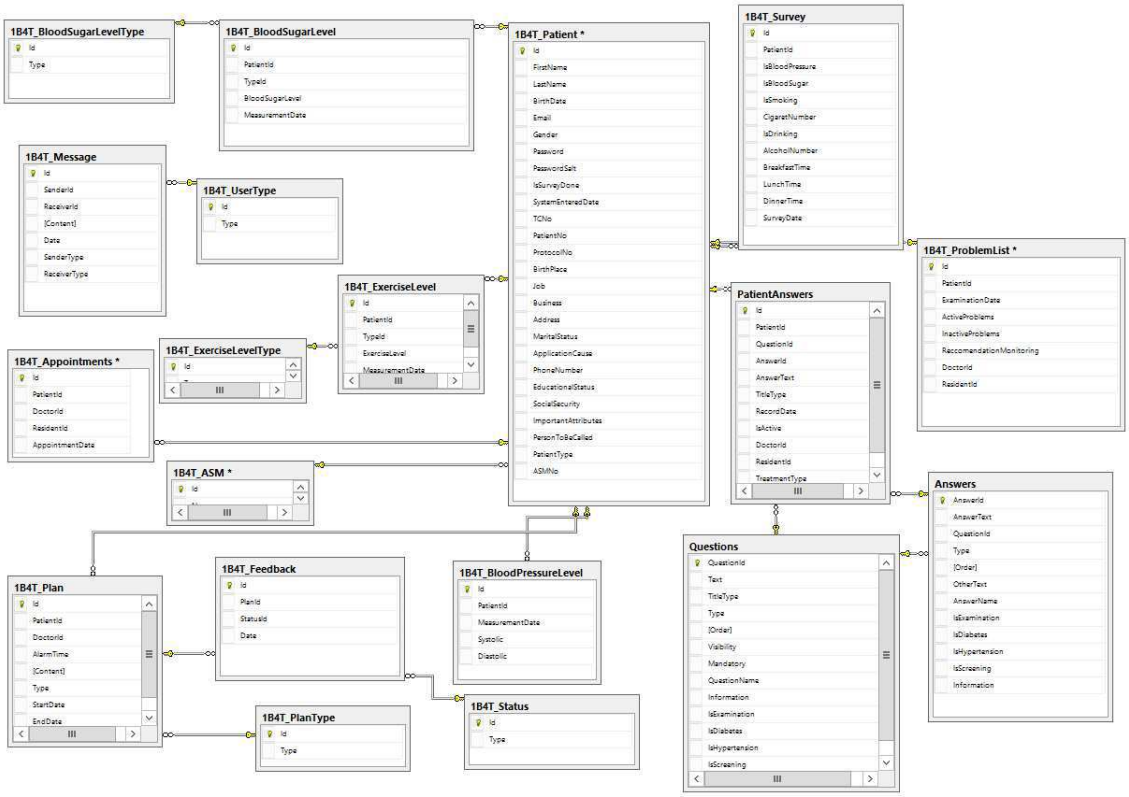


Figure 5.2 Database design of mobile health application

5.2 Web Services

Web services were used to connect database and mobile application. The values which are taken from mobile application are sent to web service. Web service executes database operation and returns a result to mobile application.

Visual studio was used for the web service development. The database model was created with using entity framework to access the database. Entity framework is an object relational mapping (ORM) framework. ORM is a technology which establishes the relationship between database and object-oriented programming.

A controller class was created and actions were written for each operation to be accessed by the mobile application. The operations were called in these actions. The method which can be post or get was determined for each action. Action name which will be used by mobile application while calling operation was determined for each action. Authorization requirement was determined for some actions. Authorization means that user must have a token to use the operation or a token must be sent with the required parameters while using the operation.

Token based authentication is used to handle security procedures and to authenticate client in a service which is based on REST architecture. RESTful services are very simple and flexible. They are built on HTTP protocol and provide client-server communication. In token based authentication, client enters its own security information and this information is sent to authorization server. If authorization server verifies this information, an http response which includes access token is returned to client. After that, the client accesses to the related services with adding an access token to authorization header of http request.

OAuth 2.0 protocol was used for authorization operations with the help of Owin library of Microsoft. Owin builds own pipeline between IIS and application and handles operations here.

5.3 Program Functions

5.3.1 Login and User Account Operations

When the users start the application, they are directed to the login screen if they have not logged in before. E-mail address and password is taken from user. If this is the first login user is directed to survey page. After that, user is directed to the main page.

To create an account, name, surname, e-mail, password, gender and birthday information is needed. After entering this information, a new account is created and system is logged in with this account. Account information can be viewed or updated later.

In forgotten password screen, e-mail is entered and a verification code is sent to this e-mail. Using this verification code, a section to determine a new password appears. After password is changed, user is directed to the login screen with a brief message.

The survey must be filled in by user at least once. Therefore, when a user registers to system, the user is directed to the survey page. Also, when the user logins to system, he/she is directed to the survey page if it was not filled in before. There are some questions like using cigarette, using alcohol, amount of using, breakfast time, etc. These questions are listed in the Table 5.1.

After filling the survey, user is directed to main page. The survey filled in by user can be displayed or updated later. While updating a survey, it is added to the database as a new survey.

Table 5.1 Survey questions

Question	Answer
Choose the type of disease	DM and/or HT
Do you smoke ?	Yes or No
How many cigarettes do you use per day ?	Number
Do you use alcohol ?	Yes or No
How many units of alcohol do you use per day?	Number
What time do you have breakfast?	Hour
What time do you have lunch?	Hour
What time do you have dinner?	Hour

5.3.2 Main Page

The main screen is the screen in which all operations are managed. There is a menu to select blood pressure, blood sugar or walking exercise screens at the bottom. Also, there is an menu to select edit profile, edit survey or log out.

5.3.2.1 Blood Pressure Measurement

In the blood pressure section, last eight measurements are displayed and when scrolled, the next eight measurements are loaded until the all measurements are displayed on the screen. When a measurement from this section is clicked, a dialog appears with information of this measurement. This value can be updated or deleted. Also, a new blood pressure measurement can be saved in this section. Date and time of measurement is also taken with systolic and diastolic blood pressure measurement values as shown in Figure 5.3. When the blood pressure data is saved, it is displayed on the screen with last measurements including it.

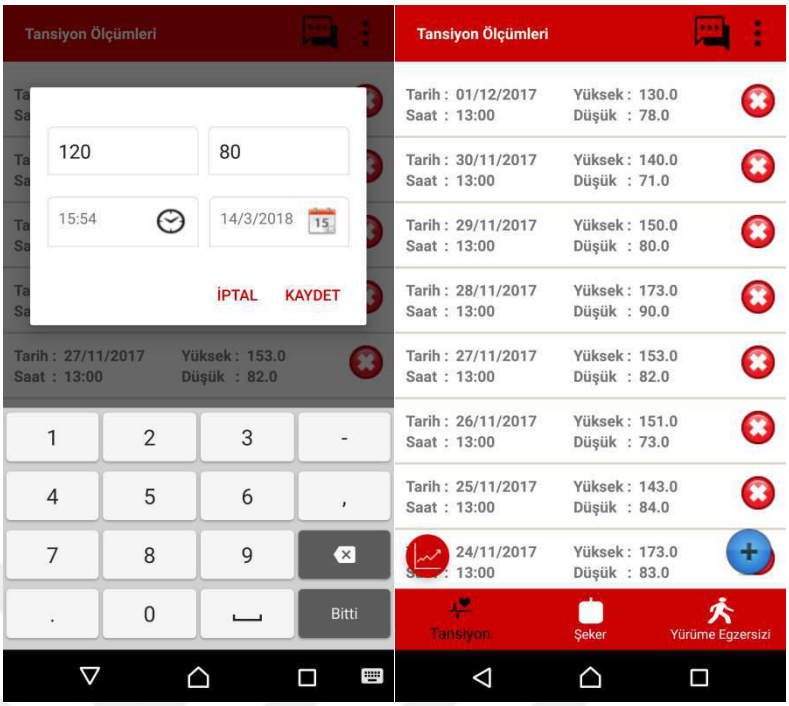
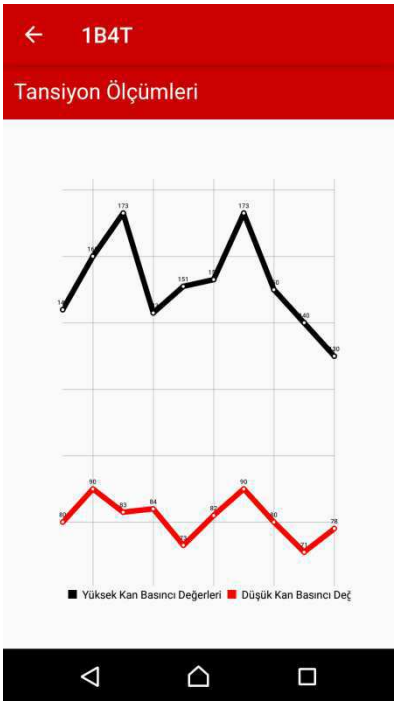


Figure 5.3 Blood pressure entry

The measurements are also graphically presented beside the list view. In Figure 5.4 an example of graphical representation of blood pressure measurements of a patient is shown.



5.4 Graphical representation of blood pressure values

5.3.2.2 Blood Glucose Measurement

In addition to the features expressed in blood pressure measurement topic, date and time of the measurement is taken with blood glucose measurement value and type (postprandial or pre-prandial). Blood glucose measurement data entry and measurement list screens are shown in Figure 5.5.

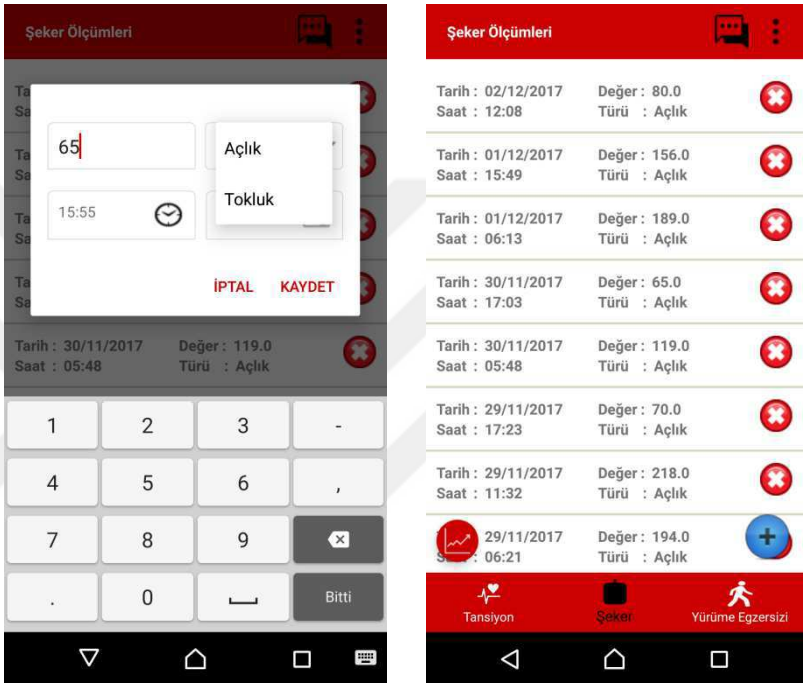


Figure 5.5 Blood glucose entry

5.3.2.3 Walking Exercise Measurement

In addition to the features expressed in blood pressure measurement topic, to save a new walking exercise, date and time of activity is also taken with value and unit which is step, meter or kilometer.

5.3.2.4 Messaging Screen

The messaging screen is the screen which allows instant communication between physician and patient. Patients display their messages and send message to their

physician from this screen as shown in Figure 5.6. If the messaging screen is not open, a notification is sent to user with the new message.

Figure 5.6 Messaging interface

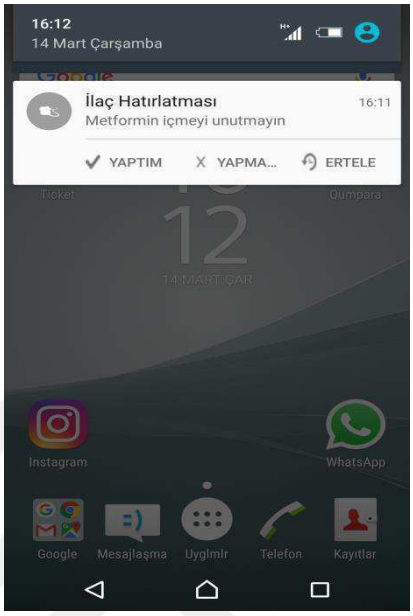


Figure 5.7 Plan reminder notification

5.5.6.5 Notifications and Feedback

The measurement, activity or medication plans which are determined by physicians are sent as notification to their patient to remind them and take feedback about whether it was done, undone or postponed as shown in Figure 5.7. Family physicians' give directives to users about their diseases from the related web page and in the mobile application; these directives are taken using web services. According to these, blood pressure, blood glucose and walking exercise planning notifications is sent to patients' phone on predetermined time with three feedback options: done, not done, postpone. User must choose one of them to close the notification.

CHAPTER SIX
EXPERIMENTATIONS AND RESULTS

The clinical decision support rule sets has been built by researcher family medicine academicians. Then, computer engineering researchers developed web and mobile based software by using these protocols. The developed software is used by physicians and patients.

6.1 Design and Settings

The study design is a parallel single blind randomized controlled trial**.** The study protocol of the trial has been published by Kart et al. (2017). The research is conducted in Dokuz Eylül University (DEU) Family Medicine Outpatient Clinic and selected family medicine units in İzmir. DEU Hospital is a university hospital in Izmir, the third largest city in Turkey. The family medicine outpatient clinic provides primary healthcare services to outpatients in the DEU department of family medicine.

The family medicine units which provide primary health care services are located widely in the settlements. There are 972 family medicine units in Izmir metropolis. They serve under Turkish Ministry of Health.

In this study, the developed CDSMS is validated in two stages for Diabetes disease. In the first stage, the understandability, usability and adequacy of the system is tested. Necessary adjustments are made in the program in accordance with feedbacks taken from physicians and patients who use the application.

In the second stage, effectiveness of CDSMS in Diabetes management is evaluated by conducting a parallel single blind Randomized Controlled Trial (RCT).

6.2 Participants and Sample Size

The study population consists of patients applied to Dokuz Eylül University Family Medicine Clinics and family medicine units in İzmir. The CDSMS which is developed in this study is validated in two stages. For each stage different numbers of samples and sampling methods are used.

6.2.1 Stage 1

In the first stage, understandability, usability and adequacy of CDSMS software is tested. In this stage, researchers from Department of Family Medicine tested CDSMS on diabetes patients. A feedback form (Appendix-1) is applied to them for measuring understandability, usability and adequacy of CDSMS. The feedback form consisting open-ended questions are used to get feedback and suggestions from the users. They are detailed in section 6.5.1.

6.2.2 Stage 2

In the second stage, the data of 3000 participants is evaluated to determine the effectiveness of CDSMS in screening. Participants, who use medicine for DM treatment, are excluded when data analysis is made for measuring the effectiveness of the system in screening.

Participants who applied to primary health care services for any reason and screened within the scope of periodic health care for diabetes, having at least one measurement of FPG (Fasting Plasma Glucose), HbA1C or PPG (Postprandial Plasma Glucose) in last six months. Participants determined in second phase are evaluated in terms of inclusion and exclusion criteria. Eligible and volunteer participants take part in the trial. Inclusion and exclusion criteria for randomized controlled trial are listed below in Table 6.1.

Patients who were diagnosed with DM among 3000 participants (new diagnosis, former diagnosis, medicine users, non-medicine users) form the population of the randomized controlled trial. The sample size evaluated by significance level p=0.05, 80% power, 25% prevalence (controlled diabetes) and odds ratio 2 is included to experimental study. In RCT studies, lost to follow up is approximately 15.0%. This rate is also taken into account when determining the sample size. The ratio of intervention to non-intervention (controls) is 1:3. About 3000 people over age 40 apply to the 10 primary health care units (In the city of Izmir in Turkey) in a month. For reaching expected number of samples, at least 14% of patients is thought to be eligible for inclusion criteria (Assuming DM prevalence approximately 14%).

Table 6.1 Inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
• Being over age 40 • Volunteer • Computer and Internet literacy • DM diagnosed or having at least one of diagnostic criteria. These criteria; • HbA1c ≥ 6.5 • FPG ≥ 126 mg / dl • 2-hour postprandial glucose ≥ 200 mg / dl • Any time postprandial glucose ≥ 200 mg / dl • Diabetes symptoms	• Having a communication problem • Type 1 diabetes • MODY type DM • Psychotic disorders • Dementia

Diabetes symptoms aforementioned in Table 6.1 are classical symptoms of polyuria, polydipsia, polyphagia or loss of appetite, weakness, fatigue, dry mouth, nocturia. Less common symptoms are blurred vision, unexplained weight loss, persistent infections, recurrent yeast infections, itching (American Diabetes Association, 2015).

6.2.2.1 Enrollment

Eligible for trial: Patients with the age above 40 who applied to family medicine units for any reason and screened within the scope of periodic health care for diabetes are eligible for the study. Guidelines determine that 40 is the age to start diabetes screening for people without having any risk factors (Türkiye Endokrinoloji ve Metabolizma Derneği, 2013) (American Diabetes Association, 2015).

Around 3000 people with age above 40 apply to the 10 family medicine units (In the city of Izmir in Turkey) in a month. Three thousand individuals were evaluated in terms of inclusion and exclusion criteria. As DM prevelance is about 14%, 420 individuals were eligible for inclusion criteria.

Excluded and refused to participate: Selected participants after being assessed for eligibility is asked about voluntariness for intervention. Their informed consents are taken. Then the participants are taken to randomization. Eighty-five patients who did not meet study criteria or refused to participate were excluded from the study.

6.2.2.2 Allocation

335 eligible participants are assigned to intervention and control groups with simple randomization using a computerized random number generator for assignment into two groups. Eighty-five patients are allocated to the intervention group and 250 patients to the control group. Three physicians treat and monitor intervention group using the CDSMS. In the control group, other 7 physicians treat and monitor without using CDSMS.

Researchers determine the random allocation sequence and make lists of sequence. These lists are given to the nurses of the family medicine center. The nurses assess the patient according to eligibility criteria and allocate eligible patients to either intervention or control groups depending on the lists.

6.2.2.3 Follow-up

Ten participants from intervention group and 24 participants from control group were lost to follow-up. The study was completed with 301 patients. Patients in both groups are followed up for 6 months. 0th month and 6th month data are compared. Consort schema (The CONSORT Flow Diagram, n.d.) of the RCT is in Figure 6.1

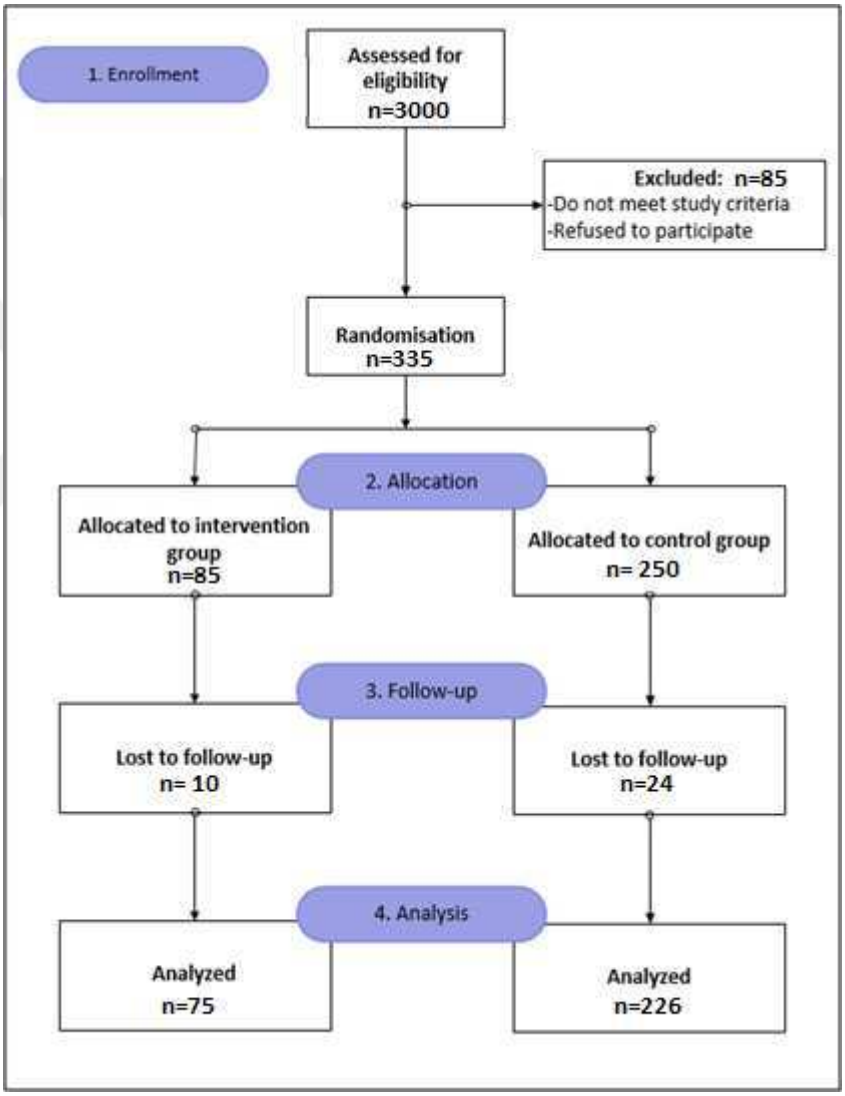


Figure 6.1 CONSORT randomization schema (The CONSORT Flow Diagram, n.d.)

6.2.2.4 Analysis

Various comparative analyzes are performed using data obtained from both groups. They are detailed in section 6.5.2.

6.3 Procedure

6.3.1 Stage 1

In the first stage, understandability, usability and adequacy of CDSMS software is tested. Three physicians test CDSMS on approximately 15 diabetes patients. A feedback form is applied. The system is revised in line with the feedback received.

6.3.2 Stage 2

At this stage, a randomized controlled trial is performed. Firstly, the physicians who manage the treatment of the patients register online through the web based portal for free. The researchers train these physicians about the use of the portal.

Patients who are referrals to selected family medicine centers for any reason receive diabetes screening using CDSMS. The patients who are diagnosed as diabetes and who were diagnosed before are recruited for trial by the physicians. The recruited patients register to the CDSMS via mobile phone with their accounts given by their physicians without paying for anything.

The proposed clinical decision support system is a recommender tool for primary care physicians to make clinical decisions on screening, diagnosis, treatment and monitoring of DM patients. Physicians input the data of patient having FPG, HbA1c or PPG test results in the last six month. CDSMS makes a statement on the diagnosis of the patient and/or the stage of the disease. The system also suggests a treatment plan for the patient. The physician evaluates the system's recommends and decides on a treatment for the patient and input his/her treatment decision. CDSMS suggests a monitoring plan to the physician. The physician evaluates the proposals and inputs the follow-up plan that he/she has decided for the patient to the system. The follow-up visits happen with the physician.

For remote monitoring of patients, the patients install the application on their mobile phone and complete the online registration process. They are trained about how to access and use the program and how to input their data into the daily program on the application. They are given a brochure which explains briefly the program. Then, usual patient examination process is completed. Patients input their measurement data (e.g. FPG, diet, exercise, weight) regularly. Through mobile application, patients can receive individualized therapy as well as alerts and notifications such as the amount and usage frequency of medicines on their monitoring process.

In this way, from mobile application, patient data is transferred to the system periodically. Regularly collected data is used for physician's evaluation. Warnings are sent to the physician and / or patient when deviations from the normal conditions (reminder for medication, elevated blood glucose, etc.) occur. In accordance with the patient data in the system, notices and short reports are created for physician and patient in certain periods of time.

For security, personal information is kept encrypted. Access rights to the system are determined by user role definitions.

When testing CDSMS, the system makes a suggestion to the physician. The physician makes his/her own decision on the patient considering the system's suggestion and his/her clinical experience. Both of the suggestion of CDSMS and physician's own decision is saved in the system and compared later. Physicians take suggestion of CDSMS but implement their decision for each case. The application is designed in this specific way in order to avoid any harm on patients.

6.4 Measures

Primary outcomes of RCT include HbA1c and Fasting Blood Glucose levels. Clinical and laboratory outcomes are face-to-face assessed, others are online self-assessed. The effectiveness of the system is evaluated by using primary outcomes. Table 6.2 lists the outcomes and measures used in this study. On screening, fasting blood glucose, HbA1c and other tests according to patients' history and physical examination is determined and implemented for each patient taken into intervention and control groups. Monthly average of FPG and PPG values of patients regularly taken from tele monitoring system are evaluated. Glycosylated hemoglobin (HbA1c) tests are done in baseline and after 6 months.

Secondary outcomes could also be used to enrich the study. This dissertation does not cover secondary outcomes. Diabetes is a chronic health problem. Emotional reactions and difficulties in adaptation in diabetic patients are the most common problems. Future concerns affect the cognitive and emotional functions and social life of patients, other than the natural distress caused by symptoms, complications, and treatments applied (Pearce, Pereira, & Davis, 2013). Self-efficacy beliefs play an important role in individuals with health problems like diabetes that require complex treatment and care, taking steps to make lifestyle changes and learning new skills to cope with the disease process. It is expected that diabetics should have sufficient self-efficacy to cope effectively with complex diabetes care and treatment. Diabetics' self-care behaviors can be improved by increasing their self-efficacy levels (Bandura, 2004; Van Der Ven, 2003) .

Secondary outcomes might include diabetes-related emotional burden and interpersonal distress sub-scales, self-efficacy for diabetes self-care, blood glucose monitoring, physical activity, medication-taking, diabetes self-care: blood glucose self-monitoring, medication-taking, physical activity, depression, anxiety, stress levels. On baseline the scales for assessing the secondary outcomes would be implemented such as Diabetes Distress Scale (Polonsky et al., 2005) Turkish version (Erkin, Ongel, Mergen, H., Yilmazer, & Mergen, B. E., 2016), Diabetes Self-

Efficacy Scale (Lorig, Ritter, Villa, & Armas, 2009). Turkish version (Mankan, Erci, Turan, & Aktürk, 2017), Diabetes Self-Care Activities Survey (Toobert, Hampson, & Glasgow, 2000) Turkish version (Kav et al, 2010) , Morisky Medication Adherence Scale (Morisky, Ang, Krousel-Wood, & Ward, 2008), The Patient Assessment of Chronic Illness Care-Patient Form (Glasgow et al., 2005) Turkish version (İncirkuş, & Nahçivan, 2011).

Participants in intervention group are given screening, diagnosis, treatment and monitoring service by the physicians using CDSMS for six months. These patients are monitored in the framework of the protocols. The control group patients receive services from physicians as they have done before without further intervention. All tests implemented on screening and baseline are repeated at the end of six months. Making comparison between the two groups, the effectiveness of the study are measured. The measures and scales used at screening (enrolment), baseline, monthly, quarterly and at the end of intervention are summarized in Table 6.3.

Table 6.2 Measures

Measurement area	**Outcomes assessed**	**Measure/s**
Demographics	Age, gender, nationality, country of birth, relationship status, employment status, health insurance	Short answer and multiple choice items
Laboratory	HbA1c level, FPG and PPG	Venous blood sample
Clinical	Height, Weight, Diabetes Symptoms, Risk Factors	Patient history and physical examination
User program evaluations	Users' program usage, perceived utility and acceptability, ease of use, user interface, and satisfaction with program	Feedback form

Table 6.3 Schedule of enrolment, interventions, and assessments

	Stage1	**Stage 2 (RCT STUDY PERIOD)**						
		Enrolment	Post-allocation					Close-out
Timepoint		0	*Baseline*	*1. month*	*2. month*	*3. month*	*4. month*	*5. month*	*6. month*
ENROLMENT									
Eligibility screen		X							
Informed consent		X							
Allocation		X							
INTERVENTIONS									
Intervention Group			←	—	—	—	—	—	→
Control Group			←	—	—	—	—	—	→
ASSESSMENTS									
Glycosylated hemoglobin (HbA1c)		X							X
Fasting Plasma Glucose		X		X*	X*	X*	X*	X*	X*
Postprandial Plasma Glucose				X*	X*	X*	X*	X*	X*
Feedback form	X								

*monthly average values of daily measurements collected by mobile application.

6.5 Statistical Analysis

Statistical analysis was performed using SPSS software. As stated in the method section, the system was tested in two stages.

6.5.1 Stage 1

For the first stage, feedback forms are evaluated qualitatively. The system has been used by experts to evaluate the overall operation and learn user experiences. In this regard, experts have shared aspects they think positively or should be improved. When assessed, the system has been dealt with in terms of efficiency, effectiveness, learnability, ease of accessibility, ease of navigation, ease of design and ease of use.

1. Efficiency: It has been seen that the information required about the patients is already being asked, removed the risk of forgetting or missing information. On the other hand, there are experts who think that questions take a lot of time and need to be simplified.

2. Effectiveness: Because of the treatment proposal of the system, most of the specialists have indicated that they are using the system easily and willingly.

3. Learnability: Users have stated that the system is easy to learn in a short period of time

4. Accessibility: Some negative feedback have been received that experts have experienced difficulties in reaching some recorded data.

5. Navigability: The users indicated that the system was easy to navigate and that the requested information was reached as soon as possible.

6. Design: Opinions were received regarding that the headings are clear, the words used are short, concise and understandable, visual integrity is complete. There are also experts who argue that it needs to be simplified.

7. Usability: It has generally been found that the use is generally easy to perform. Opinions were received that technical assistance should be provided at the points needed.

In line with the views, the system was reevaluated and necessary arrangements were made in terms of the aspects to be developed.

The revised system was used on 100 patients. The proposals were presented by the system to the physicians during the screening, diagnosis and treatment phases and the validity of these proposals was tested. In the treatment suggestions, 64% of the patients were in the 1st step treatment group, 20% in the 2nd step treatment group and 16% in the 3rd step treatment group. The system provided 94% suggestions which are the same with physicians' decisions.

6.5.2 Stage 2

The randomized controlled trial was completed with 301 patients. Seventy-five people were in intervention group and 226 people in group. At the end of the intervention, independent samples t-tests were performed to measure the difference between the intervention and control groups.

Hypothesis for independent samples t-test:

H0: With 95% confidence, the average of the two groups is similar. (M0=M1)

H1: With 95% confidence, the average of the two groups is not similar. (M0<>M1)

In Table 6.4 HbA1c group statistic and in Table 6.5 independent samples t- test HbA1c results are given.

Table 6.4 HbA1c Group Statistics

Group Statistics					
Group		N	Mean	Std. Deviation	Std. Error Mean
HbA1c	0	226	9.097	2.5479	0.1695
	1	75	7.935	2.0752	0.2396

Table 6.5 HbA1c independent samples t-test

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
HbA1c	Equal variances assumed	10.78	0.001	3.57	299	0.000406	1.16	0.32	0.52	1.80
	Equal variances not assumed			3.96	153.9	0.000114	1.16	0.29	0.58	1.74

In the table 6.5, there are two different tests. One of them is the "Levene" test and the other is the t-test. The Levene test tests the homogeneity of the variances of groups. Because the "Sig" value is 0.001 <0.05, with 95% confidence, the variances of the groups are not homogeneous.

The values in the second row are considered when the t-test is decided, as the variances are not homogeneous. As can be seen, the H0 hypothesis is rejected because the t-test has a value of 0.000114 <0.05 for "Sig. (2-tailed)". That is, "There is a statistically significant difference between HbA1c values of patients who are treated in two different groups (intervention and control) with 95% confidence."

In Table 6.4 FPG group statistic and in Table 6.5 independent samples t- test FPG results are given.

Table 6.6 FPG Group Statistics

Group Statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean
FPG	0	226	171.284	77.8738	5.1801
	1	75	133.760	60.8217	7.0231

Table 6.7 FPG independent samples t-test

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
FPG	Equal variances assumed	15.32	0.000112	3.804	299	0.00017	37.52	9.86	18.11	56.93
	Equal variances not assumed			4.300	160.76	0.00003	37.52	8.72	20.29	54.75

In the table 6.7, because the "Sig" value is 0.00012 <0.05, with 95% confidence, the variances of the groups are not homogeneous. So the values in the second row are considered As seen, the H0 hypothesis is rejected because the t-test has a value of 0.00003<0.05 for "Sig. (2-tailed)". That is, "There is a statistically significant difference between FPG values of patients who are treated in two different groups (intervention and control) with 95% confidence."

As seen in the results of both HbA1c and FPG tests, control and intervention groups are significantly different from each other. In intervention group, HbA1c and FPG values of diabetes patients are more regulated than control group. These results can explain the study’s effectiveness.

CHAPTER SEVEN
CONCLUSIONS

This study involves the first comprehensive clinical decision support system intended for diabetes and hypertension screening, diagnosis, treatment and monitoring in Turkey, for primary care physicians. Moreover, our clinical decision support and monitoring system using evidence-based guidelines is the first example for the other medical specialties providing health services to diabetes patients as well. In addition, remote monitoring of patient data and alert mechanisms are also targeted in this study. Patient adherence to treatment in medication and lifestyle changes will also be provided.

Usage of CDSMS which is developed based on current diabetes guidelines and tele monitoring system will provide patients to receive effective treatment and regular monitorization. This will reduce possible complications, hospitalization, morbidity and mortality caused by diabetes, and the costs of treatment.

Early diagnosis and protection from potential diseases may be possible with electronically monitorization of periodical screenings. This will enable patients to live longer and healthier, reduce treatment costs and prevent the labor loss.

In CDSMS, patients send measurement data regularly; receive reminder messages and motivation messages. That will increase the patients' self-efficacy. The high level of self-efficacy will be effective in reducing the emotional stress and increasing the life quality of the patient.

Another aim of this dissertation is to facilitate personal health services, reduce the costs of health care services and improve the outcomes. Each patient is a different individual. For getting the best outcomes, everyone should have a personalized care. In addition, an individualized health care solution should be the best for a given patient and not necessary for the entire population. Moreover, each individual's

preference and real world limitations are different. A human expert, such as a health care provider, can provide personalized care based on experience.

Information technologies are integrated to patient care and monitoring in primary health care services with the proposed CDSMS based on predictive modeling. A new comprehensive and integrated approach will contribute to rapidly evolving e-health technology in the world using national information and technology savings. In addition, patient data will be collected when using rule based CDSMS.

As a future study, an intelligent clinical decision support system will be developed using machine learning and artificial intelligence technologies on collected data. Ensemble methods will be applied such as random forests beside the C4.5 decision tree algorithm for prediction. Their performances will be compared. In time series forecasting, different regression methods will be applied and their performance will also be compared. In mobile health application, collecting blood pressure and blood glucose data from devices automatically instead of typing manually is another future study.

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APPENDIX 1: Feedback Form

1B4T BİLGİSAYAR PROGRAMININ KULLANILABİLİRLİK BOYUTLARINI DEĞERLENDİRME VE GERİBİLDİRİM FORMU

Sayın Katılımcı,

Bu projede, Diyabet ve Hipertansiyon Hastalığı için Tarama Tanı Tedavi ve Takip sağlamak için web mobil tabanlı kullanıcı dostu Klinik Karar Destek ve İzlem sisteminin etkinliğini değerlendirmek amaçlanmıştır. Bu amaçla bir bilgisayar programı geliştirilmiştir. Bu programın etkinliğinin ölçümünde ilk aşama olarak programın kullanılabilirlik boyutları değerlendirilecektir.

Bu doğrultuda sistemi, size verilen bilgiler doğrultusunda kullanmanızı, kullanma deneyimlerini ve görüşlerinizi aşağıdaki maddeler boyutunda değerlendirerek olumlu bulduğunuz ve geliştirilmesi gerektiğini düşündüğünüz konuları bu formda ilgili yerlere yazarak paylaşmanızı rica ediyoruz.

Bu konudaki görüşleriniz sistemimizi geliştirmemiz açısından önemli katkıda bulunacaktır. Projemize vereceğiniz destek için çok teşekkür ederiz.

Prof. Dr. Vildan Mevsim

Katılımcının Adı Soyadı: Tarih:

1. Etkinlik, verilen görev ya da işi kullanıcının eksiksiz ve zamanında yapabilmesidir. Bu doğrultuda sistemi ETKİNLİK açısından nasıl değerlendiriyorsunuz?

Olumlu Yönler:
Geliştirilmesi gereken yönler

2. Etkililik, kullanıcının, amacını kolaylıkla ve istekli olarak gerçekleştirmesidir. Bu doğrultuda sistemi ETKİLİLİK açısından nasıl değerlendiriyorsunuz?

Olumlu Yönler:

Geliştirilmesi gereken yönler

3. Öğrenilebilirlik, kullanıcının iş ya da görevi belirli süre içerisinde ve belirli yeterlilik ölçütlerinde gerçekleştirebilmesidir. Bu süreç belirli öğrenme etkinliklerini de gerektirebilir. Bu doğrultuda sistemi ÖĞRENİLEBİLİRLİK açısından nasıl değerlendiriyorsunuz?

Olumlu yönler:
Geliştirilmesi gereken yönler:

4. Erişim Kolaylığı, kullanıcının amacına uygun olarak sitede istediği yere kolaylıkla ve en az kısıtlama ile erişebilmesidir. Bu doğrultuda sistemi ERİŞİM KOLAYLIĞI açısından nasıl değerlendiriyorsunuz?

Olumlu yönler:
Geliştirilmesi gereken yönler:

5. Gezinme Kolaylığı, kullanıcıların sitede yardıma en düşük seviyede ihtiyaç duyarak, en kısa sürede istenilen bilgiye erişebilmeleridir. Bu doğrultuda sistemi GEZİNME KOLAYLIĞI açısından nasıl değerlendiriyorsunuz?

Olumlu yönler:
Geliştirilmesi gereken yönler:

6. Tasarım, kullanıcının site ile etkileşimlerini kolaylaştıracak görsel düzenlemelerin bütünüdür. Bu doğrultuda sistemi TASARIM açısından nasıl değerlendiriyorsunuz?

Olumlu Yönler:
Geliştirilmesi gereken yönler

7. Kullanım Kolaylığı, kullanıcının siteyi, düşük seviyede yardıma ihtiyaç duyarak, istekli ve amaçlarına uygun olarak kullanabilmesidir Bu doğrultuda sistemi KULLANIM KOLAYLIĞI açısından nasıl değerlendiriyorsunuz?

Olumlu Yönler:
Geliştirilmesi gereken yönler

Diğer Görüşleriniz:

Teşekkür ederiz.