

Research Article

Remote Patient Monitoring of Patients with Complex Medical Conditions

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Abstract

Remote patient monitoring is frequently used to monitor patients with chronic disease, but patients are often only monitored for a single disease (CHF, COPD, diabetes) using systems designed to monitor only parameters for that disease. However many patients have multiple diseases that must be managed together; systems need to be designed to monitor a multiplicity of parameters. Moreover most patients are elderly and are averse to technology, and so the system has to be designed to be extremely simple to use. We describe our system, designed for simplicity of use and to support multiple types of device to monitor complex conditions. We describe how IEEE 11073 standards were used to integrate proprietary devices to our gateway to create a platform that is plug-and-play interoperable with our data server. We present preliminary results from our clinical study monitoring 68 CHF patients who were taking daily measurements of blood pressure and weight to investigate effects of behavioral change during Ramadan. There was a small decrease in mean diastolic and systolic blood pressure from pre-Ramadan to Ramadan that was significant (diastolic 131.8, 127.0, $P=0.0005$; systolic 71.4, 69.1. $P=0.008$), however there was no significant change from Ramadan to post-Ramadan ($P=0.4$). There was also a reduction in the number of incidents of systolic and diastolic blood pressure exceeding threshold values from pre-Ramadan to Ramadan.

Keywords

Remote Patient Monitoring, Telehealth, CHF, Plug and Play Interoperability, Medical Device Standards, IEEE 11073

1. Introduction

Chronic disease is becoming increasingly prevalent as the population ages. For example 6.9% of the population (5.5 million patients in Turkey) has Congestive Heart Failure (CHF) and 11.7% of the population (9 million people in Turkey) has Chronic Obstructive Pulmonary Disease (COPD), with many having multiple diseases. Turkey has the additional issues of being a large, sparsely populated country, with many people living away from the few main cities. There are relatively few tertiary care hospitals to care for the more serious patients, for example, the next nearest to Samsun is Ankara

400km distant. This means many patients live far from the hospital (200km is not unusual) and in remote villages. A typical out-patient appointment may require 3 hour car journey to the hospital, 1-2 hour wait in out-patients, only for a 10 minute appointment to be informed all is well. Patients are elderly, so a relative will need to take a day off work to bring them to the hospital. This makes patients reluctant to visit hospital if feeling unwell. Patients may not be aware of deterioration and so delay coming to hospital until it is serious.

Remote patient monitoring (RPM) provides a method to

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collect regular (daily) clinical measurements from patients in their home that allows the clinician to monitor the condition of the patient. Trends and changes in the data can be used to determine if there is deterioration and prompt intervention in management and therapy [1].

With the ever increasing burden on health services to manage chronic disease, together with scarcity of clinicians, RPM has been investigated to determine its ability to reduce hospital admission, reduce length of stay, reduce clinical contacts, reduce use of clinical resource, and reduce cost [2]. However results are mixed and outcomes are dependent on how and where the technology is used. It is also the case that RPM is a diagnostic tool and outcome will depend on the intervention. The greatest potential appears to be when used in remote geographic areas where patients live significant distance from the hospital.

2. System Design

We have considered multiple aspects in our approach to the design of the system:

- Simplicity for the user;
- Monitor multiple diseases;
- Complexity in the number and types of device;
- Integrate devices with proprietary protocols;
- Provide plug-and-play interoperability in the gateway.

2.1. Simplicity for the User

The majority of chronic disease patients are elderly (>70). They tend to be technology illiterate and averse. A significant number of elderly women in Turkey are illiterate. Many have poor eyesight and may have limited dexterity through arthritis. Devices need to be large and extremely simple to use. The user interface needs to be bold and comprise a simple indication of working or not working. In our design a red Light Emitting Diode (LED) indicates the gateway is not connected to the network (Figure 1), a green LED indicates the gateway is connected to the network (Figure 2), and the LED flashes green when data is being transmitted.

An important aspect to be considered in the design of the system is that patients may be asked to take measurements for extended periods and so it must be quick and simple to take measurements. A further aspect is that patients do not want to be stigmatized, and so the gateway needs to be designed so that it and the medical devices can be located in an unobtrusive location and out of sight of visitors.



Figure 1. Simple interface.

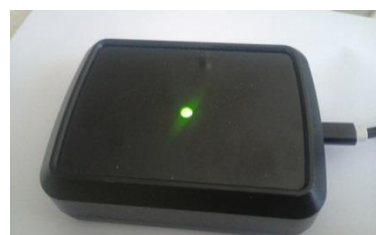


Figure 2. Simple interface.

A further consideration expressed by patients is that they do appreciate constant reminder of their disease; they do not want frequent health messages and adapt their daily routines to manage their condition [3].

The elderly patients continue to live in isolated villages in remote regions. These patients do not have access to broadband and so gateways need to be self-contained. The devices and gateway are given to patients as a kit in the hospital to take home, so must be simple to install by the patient or family. We therefore employ cell technology within the gateway and use commercial M2M services to provide secure communication for the data from device to the server.

2.2. Monitoring Multiple Complex Conditions

Typical RPM systems are designed to monitor a single disease, or small number of diseases, thus they integrate only a limited set of devices.

The aim of our project was to develop monitoring for as wide a range of diseases as possible, and thereby support monitoring the multiple complex conditions encountered in many chronic disease patients. We therefore determined and integrated devices to provide pertinent clinical measurements. The diseases for which we have developed support and the devices are given in Table 1.

Table 1. Diseases to be monitored.

Disease	Disease	Device
Anti-coagulation		INR PT
Congestive Heart Failure	CHF	Blood Pressure

Disease	Disease	Device
Chronic Obstructive Pulmonary Disease	COPD	Weigh Scale
Diabetes		Pulse Oximeter
Gestational Diabetes		Blood Glucose
Hypertension		Blood Pressure
Idiopathic Pulmonary Fibrosis	IPF	Blood Glucose
Infection		Blood Pressure
Pre-eclampsia		Pulse Oximeter
		Temperature
		Urine Protein
		Blood Pressure

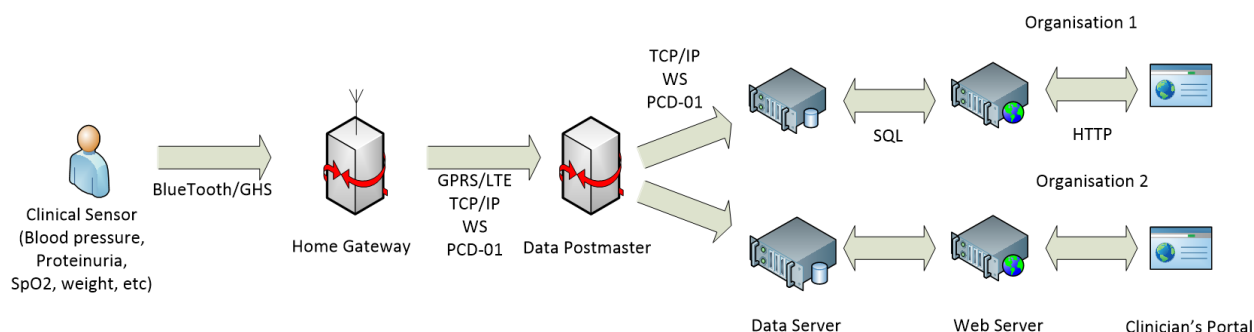


Figure 3. System Architecture.

2.3. System Architecture

Our system architecture (Figure 3) is complex in order to provide simple management of gateways, whilst supporting multiple organizations. We use the concept of the postmaster so that all gateways can be configured with a single set of parameters to reduce management of the gateways in the field.

The postmaster uses the unique identification of the gate-

way (EUI-64) in an incoming message to direct the measurement to the separate database for each registered organization. Each organization then has its own web server for the clinician to access data and to manage patients. The data server uses the extended unique identification of the device (EUI-64) to place the incoming measurement into the record of the registered patient. This approach means that measurements contain no patient identifiable information.

2.4. Integration of Devices

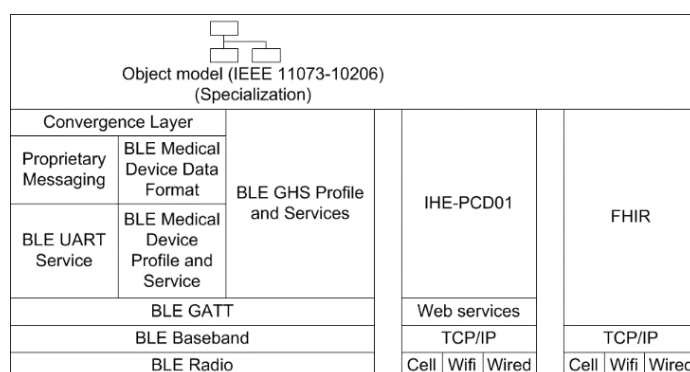


Figure 4. Integration of Devices.

We have integrated multiple types of device and several instances of each device type to demonstrate integration of devices to the platform. The devices currently integrated to the platform are listed in [Table 2](#).

Table 2. Devices Integrated to Gateway.

Type	Model	Protocol	Specialization
BG Meter	Bioland G-427B	Proprietary	11073-10417
BG Meter	Lifecek TD-4277	Proprietary	11073-10417
BG Meter	Taidoc TD-4266	Proprietary	11073-10417
BG Meter	Roche Accuchek	Bluetooth	11073-10417
BP Meter	Bioland 2006-2B	Proprietary	11073-10407
BP Meter	AND UA-651 BLE	Bluetooth	11073-10407
Urine Analyser	Contec BC401	Proprietary	11073-10422
Pulse oximeter	Contec CMS 50D-BT	Proprietary	11073-10404
Pulse oximeter	Nonin 3230	Proprietary	11073-10404
Thermometer	Genial Wearable	Proprietary	11073-10408
Weigh scale	Unique CF398BLE	Proprietary	11073-10415
Smart ring	Kingstar	Proprietary	11073-10441
Room temperature	Texas TM101	Proprietary	11073-10471
PT INR		Proprietary	11073-10418
GHS	Philips emulator	GHS	Device dependent

Integration of devices is achieved by using a common object model ([Figure 4](#)) based on IEEE 11073-10206 [\[4\]](#) and IEEE 11073-10101 nomenclature [\[5\]](#) to represent semantics. The majority of commercial devices are based on Bluetooth Low Energy (BLE) but use a proprietary protocol for the data. Our gateway includes a convergence layer that interfaces each proprietary device to the object model.

We interface devices that comply with BLE medical device profiles. However each BLE medical device profile has its own format for data and so requires a separate convergence interface.

We have implemented an interface for devices that comply with the BLE General Health Sensor (GHS) profile. This includes the GHS service and several other BLE services. The advantage of GHS is that it is based on the IEEE 11073-10206 object model and IEEE 11073-10101 nomenclature, and so maps directly to the object layer of the gateway without need of a convergence layer.

2.5. Plug-and-play Interoperability

We map all devices to the same common IEEE 11073 object model of [Figure 3](#) using IEEE 11073-10101 nomenclature. This gives the advantage that the object model can be mapped

transparently into an IHE PCD-01 message [\[6\]](#) (a profile of HL7 [\[7\]](#)) that is sent to the data server ([Figure 2](#)). We have designed the database schema so that the contents of the PCD-01 message can be mapped transparently to the fields of the database. In this way new types of device can be integrated to the platform without need to change the database schema, supporting the concept of plug-and-play semantic interoperability.

3. Methods

Our system has been designed specifically for use in projects that will monitor patients with chronic disease. Patients are elderly, many have impaired eyesight and we have patients who are illiterate. They have little or no experience with technology and many are averse. Numerous patients live more than 100km from the hospital.

Our first project is monitoring 68 CHF patients. Patients attending an appointment in outpatient's clinic or being released from hospital are given a kit to take home that includes a gateway, blood pressure monitor, and weigh scale. Patients are registered on the system and given instructions on how to use the devices and install the gateway. Patients are asked to make at least one measurement each day; data being sent

automatically to the data server. Data from all patients is checked at least once per day.

The aim of the project is to determine how the measurements may be used to best manage the patients for deterioration as seen by hypo- and hypertension. Thresholds have been agreed, and patients with values exceeding limits are referred to the cardiologist for investigation.

Our second project will monitor patients with hypertension and high risk pregnancy that includes pre-eclampsia and gestational diabetes. Hypertension patients will be given blood pressure monitor; pre-eclampsia patients will be given blood pressure monitor and urine analysis device; gestational diabetes patients will be given glucose meter.

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Figure 5. Patient Management.

The clinician portal provides access to the patient data. It shows incoming daily data (Figure 5) and allows the clinician to look at the data of an individual patient in tabular (Figure 6) and graphical (Figure 7) form.

Date	Time	Weight
28/02/2024	08:10	72.20
27/02/2024	20:17	73.20
27/02/2024	20:16	74.90
21/02/2024	08:32	73.90
20/02/2024	08:06	72.00
20/02/2024	08:06	72.00
19/02/2024	19:27	72.40
19/02/2024	19:26	72.00

Figure 6. Tabular Display of Patient Data.

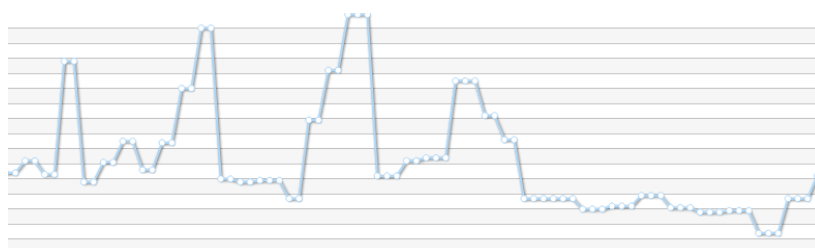


Figure 7. Blood Glucose following change to medication.

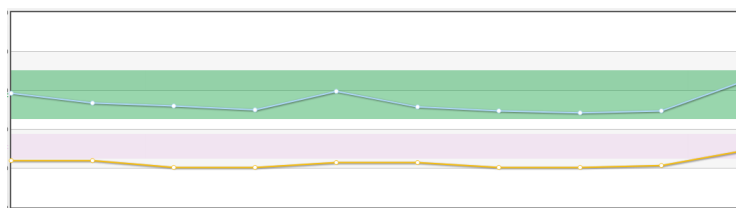


Figure 8. Blood Pressure variation in CHF Patient.

Our project started collecting data from patients in January 2025. Ramazan (Ramadan) in 2025 occurred March 1st to 29th. During this period there are marked changes to the dietary habits of patients; they fast from sunrise to sunset and the types of food may change (e.g., increased salt). We decided to investigate the effect of these dietary changes on CHF patients.

4. Results

Currently there are 68 patients enrolled in the study, 40 male and 28 female, age 43-87 y, mean 71.2 ± 10.2 y. All are registered with the cardiology department of Ondokuz Mayıs University hospital for CHF.

Table 3. Mean and Standard Deviation of Periods.

	Pre-Ramazan		Ramazan		Post-Ramazan	
	Dias	Sys	Dias	Sys	Dias	Sys
Mean	131.8	71.4	127	69.1	126.6	68.9
S.D.	26.2	16.1	21.3	14.5	19.3	14.2
Maximum	242	147	209	165	194	134
Minimum	69	32	63	32	74	33

Table 4. T-test comparison of Periods.

Pre-Ramazan-Ramazan		Ramazan-Post-Ramadan	
Dias	Sys	Dias	Sys
0.0005	0.008	0.4	0.4

Table 5. Number of Incidents.

Threshold	Number measurements	Diastolic		Systolic	
		200	80	100	50
Pre-Ramazan	482				
Number		4	3	28	21
Percentage		0.8	0.6	5.8	4.4
Ramazan	677				
Number		2	1	19	21
Percentage		0.3	0.1	2.8	3.1

Threshold	Number measurements	Diastolic		Systolic	
		200	80	100	50
Post-Ramazon	832				
Number		0	2	15	61
Percentage		0.0	0.2	1.8	7.3

CHF patients exhibit both a large range and variation of blood pressure, and may have sudden significant changes. They will have blood pressure values that exceed high and low thresholds and will require intervention in therapy. We therefore considered the statistics of diastolic and systolic blood pressure for the periods pre-, during, and post-Ramazan that included:

- Mean and standard deviation;
- Maximum and minimum;
- Number of incidents;
- Histograms;
- Cumulative frequency graphs.

As our project progressed, we collected more data points in each period, and so we normalized the histogram values to give comparative graphs.

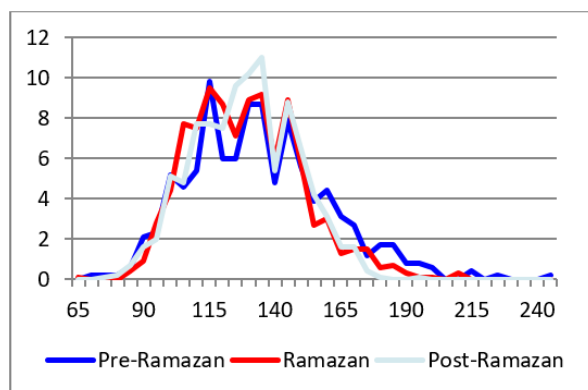


Figure 9. Distribution Diastolic Blood Pressure.

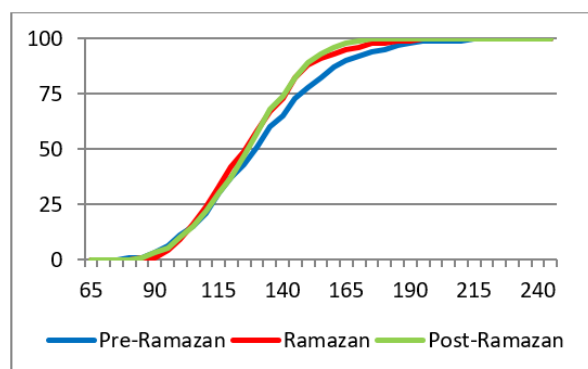


Figure 10. Cumulative Frequency Diastolic Blood Pressure.

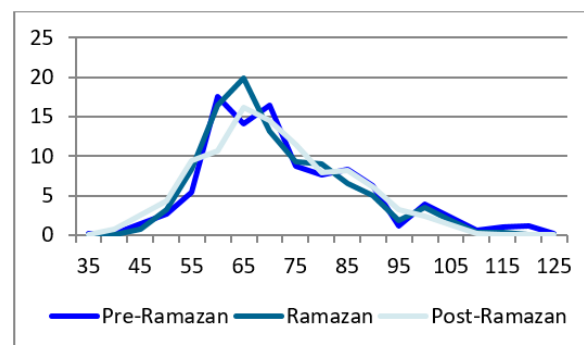


Figure 11. Distribution Systolic Blood Pressure.

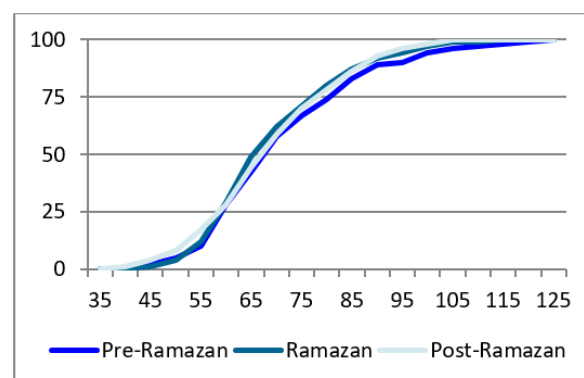


Figure 12. Cumulative Frequency Systolic Blood Pressure.

5. Discussion

There was a small decrease in mean diastolic and systolic blood pressure from pre-Ramazan to Ramazan that was significant (diastolic 131.8, 127.0, $P=0.0005$; systolic 71.4, 69.1, $P=0.008$), however there was no significant change from Ramazan to post-Ramazan ($P=0.4$) (Table 3). This decrease is explained in the figures for distribution (Figure 9, Figure 11) and cumulative frequency (Figure 10, Figure 12) where a reduction in the number of high values is observed, with corresponding reduction in standard deviation.

A similar reduction in blood pressure is reported the systematic review by Mazidi [8] and in the study by Nematy [9].

The reduction in high diastolic and systolic blood pressure values resulted in a decrease in the number of incidents of values exceeding set thresholds (Table 5). There was also a

decrease in the number of incidents due to low diastolic blood pressure and low systolic blood pressure; however the latter rose post-Ramazan.

6. Conclusions

We describe a platform that has been designed specifically for use by the elderly and integrates multiple devices to support monitoring patients with complex conditions and co-morbidities. We adopt IEEE 11073 object models and IEEE 11073-10101 nomenclature in our gateway to create plug-and-play semantic interoperable messages to forward to the data server using IHE PCD-01.

The platform is currently being used to monitor CHF patients, many living far from the hospital with no reported issues regarding use.

Preliminary analysis of our data has shown there is a small difference in blood pressure, distribution, and incidents between pre-Ramazan and Ramazan, however there is no significant difference in blood pressure, distribution, and incidents between Ramazan and post-Ramazan. We therefore conclude that behavior changes during Ramazan have no adverse effect on the condition of CHF patients.

This is first study that uses daily measures of blood pressure rather than small number of measurements in the clinic. Further analysis will be required to determine if this reduction is maintained.

Abbreviations

BG	Blood Glucose
BLE	Bluetooth Low Energy
BP	Blood Pressure
CHF	Congestive Heart Failure
COPD	Chronic Obstructive Pulmonary Disease
EUI-64	Extended Unique Identifier
GHS	General Health Sensor
IHE	Integrating the Healthcare Enterprise
INR	International Normalized Ratio
PCD	Point of Care Device
PT	Prothrombin Time
RPM	Remote Patient Monitoring

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Author Contributions

Malcolm Clarke: Conceptualization, Software, writing

original draft

Hulya Gokalp: Principal investigator

Omer Gedikli: Cardiologist, patient management

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Conflicts of Interest

The authors declare no conflicts of interest.

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