Architecture Description
for
Smart Home Medication Adherence

Submitted by

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Glossary

Terminology/ Abbreviation	Meaning
SHMA	Smart Home Medical Adherence
SOA	Service Oriented Architecture
CRUD	Create Read Update Delete
DB	Database
IoT	Internet of Things

1. Introduction

The Smart Home Medication Adherence (SHMA) system is a subscription service which organizes patients' prescribed medication taking activities. This system provides a solution for patients with poor adherence to medication regimens. This document is to describe the architectural decisions, architecture styles, and viewpoints of the different stakeholders of SHMA system. This will help different stakeholders to see how there concerns will be addressed in architecture of the system and provide the feedback if there are any untackled concerns in architecture which needs attention.

1.1 Background

The challenges of medication adherence are very common and there are products available in the market like smart pill organizers, these products have few disadvantages such as:

- Lack of communication among doctors, patients, and other stakeholders. To ensure a patient's adherence to medication regimens, the collaboration among doctors, patients, caregivers, drug stores, and financial providers is the key to lead to the success.
- Lack of compliance data about whether patient taking drug on time or not. [1] Although there are smart pill organizers on the market which can remind patients to take drugs and send updates about patient taking drug or not, the data for whether patients taking drugs on time is not stored in a centralized location. When doctors think about treatment plan for patients, looking at the historical data to see whether patients taking drugs on time or not can help doctors to come up with a better plan for patients.
- The method to determine patients enable compliance or not is not applicable to some patients. Most products use methods like scanning medication box barcodes [2] as a proof of patients taking drugs. However, if patients are limited in some way with regards to learning new user interfaces, the current methods can't be used by these patients.
- The patient's monitoring data is not available real-time to various concerned parties. Most of the current products are designed to help the tracking for patients only [3]. The other concerned parties like doctors and/or drug stores can not get the real-time data about the patient's drug taking monitoring activities.
- When there are changes regarding to prescription or timing, the setting needs to be changed manually. Although many current products are programmable, patients or caregivers still have to change the setting manually when needed.
  The SHMA system is designed to address these issues.

To improve the current products, the goal of the project is listed below:

- Facilitating the communication among various concerned parties. Patients, doctors, caregivers etc can communicate on the SHMA platform.
- Providing real-time patient drug taking monitoring data to all concerned parties, notifying them when there is emergency (i.e. patients not taking drugs), and storing data in a centralized location for easy and secure access.

- Any changes regarding to the medication regimens are done automatically. Once a patient subscribes to SHMA system and has the customized drug dispenser installed, the doctor can send the prescription and the drug store can send out drugs and set up timing through the internet. There is no need to manually change the setting on the hardware.

1.2 Overview

The SHMA system (see Figure 1) is a subscription service. To use the SHMA system, patients have to first subscribe the SHMA service and then get the customized hardware installed. After that, patients or their caregivers only need to provide some information to the system (like who is the doctor etc) then the SHMA will ask all the stakeholders to register for an account. The system is then ready to go.

The customized hardware system includes sensors, video recorders, and drug dispensing unit. It alerts patients when needed and video records their drug taking activities. The video data is sent to the local processing unit which can determine if the patient takes the drug or not. The result data is then sent to the cloud for storage. The hardware has another recording feature for tracking refills. It monitors the pill inventory and sends data to the local processing unit. The local processing unit can decide when the inventory is low and send data to the cloud. The cloud service can notify drug store for refilling.

Besides, doctors/caregivers/drug stores/financial providers can access patient's drug taking data and send requests by using their computers, mobile phones, or smart devices (Alexa or Google Home). Depends on their roles, each party has different authorized levels and interfaces regarding accessing data, sending requests, or modifying information. For example, only doctors can send requests to change prescriptions or only drug stores can send requests to refill drugs. Finally, if there is any issue regarding IT infrastructure, feedback, or emergency etc, the system management (i.e. DevOps) group can assist any kinds of questions.

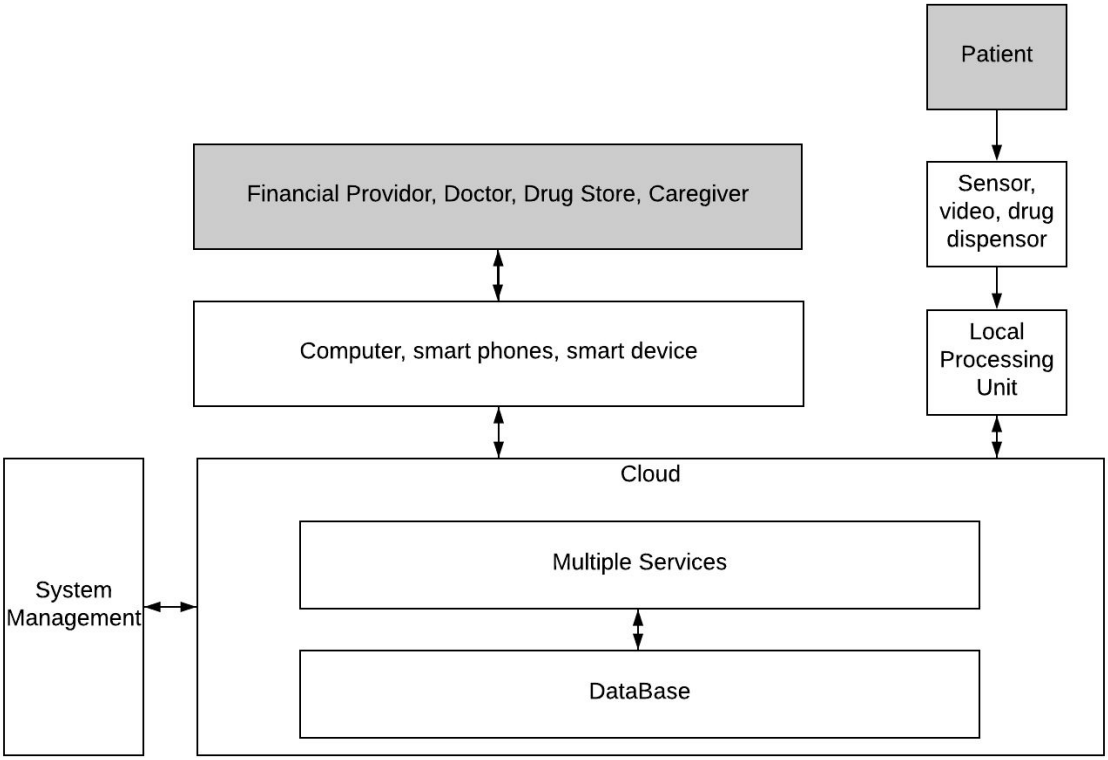


Figure. 1: High level flow diagram of SHMA

1.3 Stakeholder

The stakeholders of this system are listed below:

1) Patients - Person whom system will monitor for prescription drugs compliance
2) Doctor - Person who will add/update the prescription in system.
3) Caregiver - Person who monitors if patient is complying with drug compliance and will answer their concerns, can be family member or nurse
4) Finance provider - Person/entity who will buy the system for the patient, can be a family member, insurance provider or government support.
5) Drug store - Will be responsible for refill of the drug dispenser based on doctor's prescription.
6) DevOps - Manages the technical tasks such as security updates, new features release etc)

1.4 Architecture design strategy

The design strategy used in the project is **bottom-up design** (compositional strategy). First, we started from the requirements and listed out the requirements which are related to the architectural decisions (see Figure. 2). Next, we generated low level components from these architectural related requirements (see Figure. 3). Last, we grouped components with similar architectural functions to generate the major components (user interface, database, and middle layer services) and connected those components to form a block diagram(see Figure. 4).

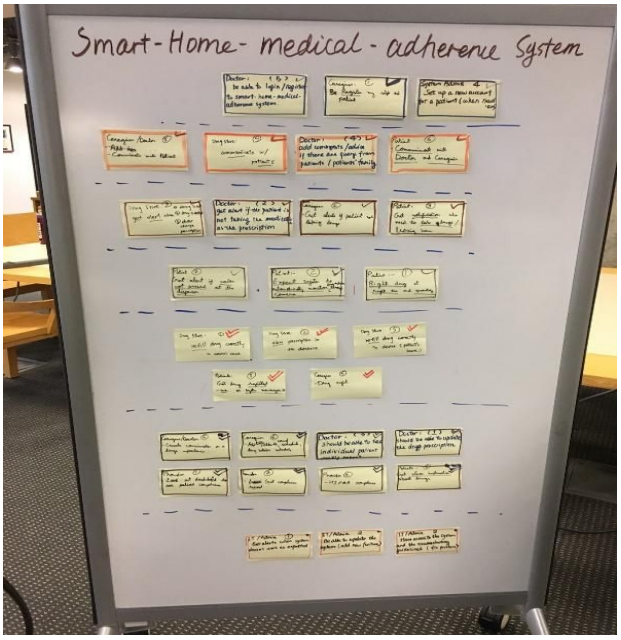


Figure 2. From requirements to components

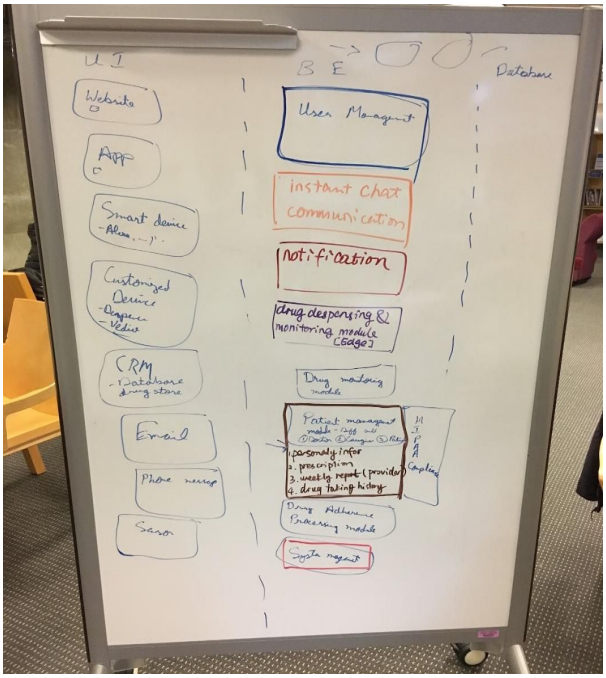


Figure 3. Grouping components

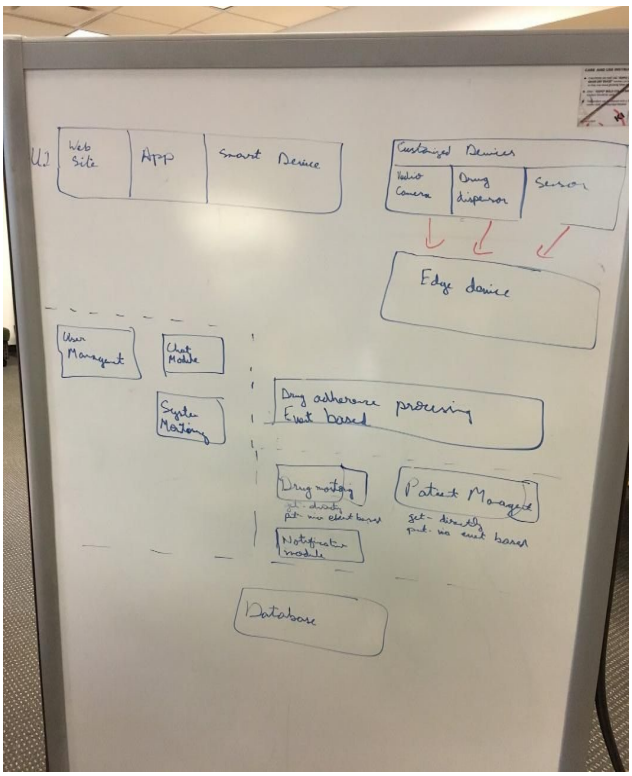
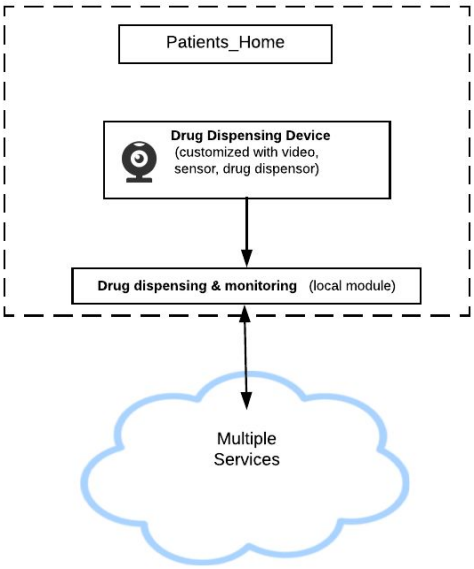


Figure 4. Generating major components

2. Architecture Description

2.1 Viewpoints and Views

Viewpoint Element1	**Description**
Stakeholders	**Patient**
Viewpoint Concerns	1. Privacy: Patient doesn't want his private data collected via sensors or video camera out of his home. He also doesn't want his medical data to be available to anyone else other than the authorized people 2. Usability: If the patients are not able to learn traditional user interface (like computer and smartphone). Patients can interact with the system through some smart device (google home, Alexa) which is very simple to use or through their caregiver to access the system. 3. Support: Patient needs to be able to get help for his medications and using the drug dispenser system/software using smart device.

	4. Bad internet connection: Patient needs to be able to use drug dispensing unit even if there is internet connection breakdown 5. Device breakdown: System should be able to reboot/replace/repair the dispenser system if there is a breakdown
View Description	**Privacy**: In Order to maintain the privacy data extracted from sensors and video camera is processed at patient's home on a local processing device(figure 5). User compliance data is extracted and sent to backend system. This lead to architecture decision for a fat client(local processing device)- fat server.  Figure. 5: Local processing module interaction with Cloud Services Furthermore, when system is communicating among its services or with an external client it will encrypt the communications via HTTPS. System has a account management service(figure 6) which will manage authentication and authorization for different users. Whenever user attempts to request different service, the user management service will be called. Based on the user id it will generate a token. This token will be used to perform CRUD operations in the system for different services. This service could be build or buy. There are advanced solution available in the market at cheaper rate, so instead of building it we will buy this service from Azure Active Directory.

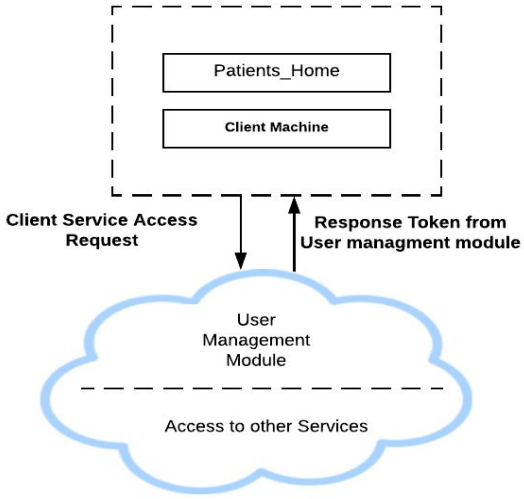


Figure. 6: User Management Module interaction

Usability: System architecture is designed to avoid using traditional interfaces(like website, mobile app) for patient. Patient will have a drug dispenser device(figure 7) which will get data about patient's medication schedule. Whenever it is time to take a drug, patient will get a notification on his mobile phone that he needs to go to the drug dispenser. Dispenser will dispense required drugs and will record a video.

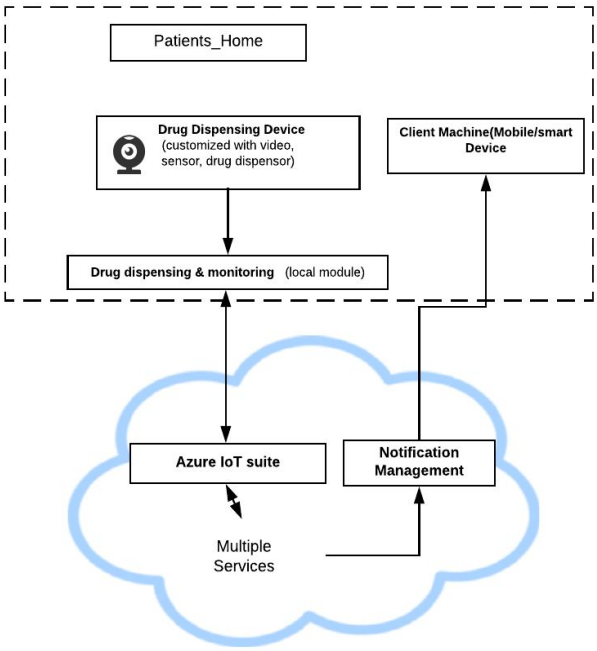
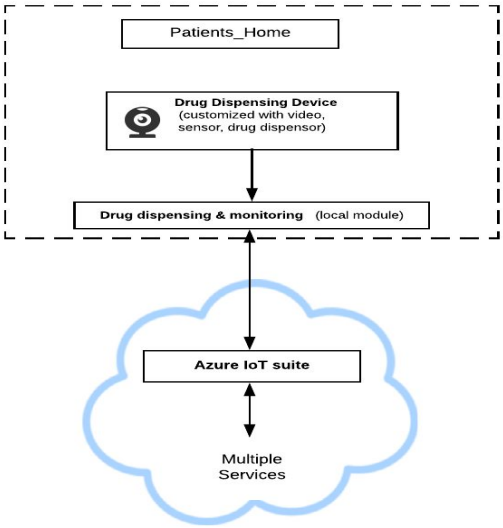


Figure. 7: Patient view for the system

Support: Customer enquiries will be routed to Customer support engineer through the menu available from customers dashboard. Patients can also send messages to their doctor and caregivers. This is achieved by using the instant message module. All the data sent via instant message is saved in system database for later retrieval. The instant messages service can be bought rather build which will be a cheaper option. Patients can also seek support/send (receive) messages via smart speaker devices like Alexa and Google home, if he/she not inclined to use the website or mobile app.

Bad internet connection: Drug dispensing unit is designed in such a way that it can function even if patient has a bad internet connection. It only needs to get medication schedule from the system the first time or when a change is made by the doctor/caregiver. Furthermore it only sends a very small payload(yes/no) if the patient is taking medicines on time. If internet connection is not available for some time, it can cache the data on the local device and send it when connection is available.

Device breakdown: Using an Azure IoT framework allows local(dispensers) devices(figure 8) to have a twin of each device in cloud. When the device goes down all the changes are applied to the twin clone. And when it is back the twin sync in with the local(dispensers) device.

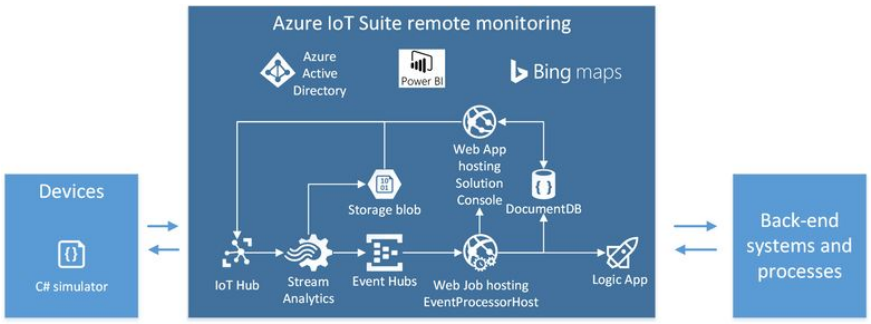
	 Figure. 8: System interaction with Azure IoT Suite

Viewpoint Element2	**Description**
Stakeholders	**Doctor and Caregivers**
Viewpoint Concerns	1. Autonomy: Doctor/Caregiver receives alert 2. Data accessibility: Doctor/Caregiver can get patients data 3. Usability: User interface is easy to use
View Description	**Autonomy**:System is designed with appropriate alerts provided to doctor regarding patient compliance. This is achieved via the drug monitoring processing module which is part of the Azure IoT module - defined in the DevOps stakeholder.. **Data Accessibility**: Doctor can do CRUD operations on patients medical data in a secure fashion. The data gathered through sensors will be made available to the Doctor/Caregiver on a dashboard. All the patient related data will be available in Patient Management module which will be SOA. The data will be stored in Azure CosmosDB. **Usability:** Doctor/Caregiver will be able provided a dashboard which they can customize based on their needs.

Viewpoint Element 3	Description
Stakeholders	**Provider(family,government,Insurance)**
Viewpoint - Concerns	1. Regulatory compliance: Providers are concerned about meeting the government standards e.g. HIPAA 2. Affordability: System should not be expensive for end users.
View Description	**Regulator Compliance**: In Order to be inline with regulatory compliance system will be implemented with the HIPAA compliance regulation. This will be achieved using Azure cloud and storing data in Azure CosmosDB (DocDB) which is HIPAA compliant.[4] Reference : https://adeliarisk.com/is-microsoft-azure-hipaa-compliant/. **Affordability**: The system architecture uses available services in the marke. COTS solution will be used to minimize initial build cost.It's Buy versus Build decision.While integrating the existing solutions in SHMA system standard and regulations will be followed.

Viewpoint Element 4	Description
Stakeholders	**Drug Store**
Viewpoint - Concerns	1. Usability, and usage: Customization and integration of the available drug dispensing device with SHMA.
View Description	**Usability and Usage**: Different drug dispenser units available in the market should be able to connect with the system.SHMA components are loosely coupled and have modular structure which makes easy integration of new device with SHMA system.

Viewpoint Element 5	Description

Stakeholders	DevOps
Viewpoint - Concerns	1. Scalability: During operation the system should be able to scale up and scale down if the load (calls) on the system increase (decrease). System should also be able to handle any number of local (edge) medication dispenser devices 2. Software modularity and reuse: System needs to be designed in a modular format, so it is easier to update the system 3. Portability: Components of the smart home medical adherence application can be deployed across different platforms 4. Migration and interoperability: Components are designed in such a way that they can interact with each other as well as should be easy to migrate in new environment. 5. Development Approach: Deploying updates 6. System Health monitoring: The system and microservices should be designed in such a way that there health can be monitored
View Description	**Scalability**: In order to address scalability, the architecture is designed in a RESTFUL API SOA architecture, where different modules are designed in a modular way and they can be individually scaled up and down. Furthermore the services are deployed in a cloud, where resources can be increased and decrease as need be. Furthermore database being used is cloud Azure docDB which can be replicated to allow for better scalability. In order to allow local (edge) medication dispensers to be scalable, Azure IoT suite(figure 9) will be used which, manages the physical devices, routes the event sent via the device, processes it and then makes a call to other backend services.  Figure. 9: Azure IoT Suite Architecture [5] **Modularity**:We have used SOA for backend services, which allows our architecture to be agile, modular and loosely coupled. This allows us to but external services and modules and integrate it in our system as need be.

Portability:Backend of the system will be interacting with RESTFUL API which is platform independent

Migration and interoperability:Backend system will be SOA architecture, which is easy to migrate to a different technology in future.

Development approach: Uses cloud app services provides infrastructure to constantly make updates to the services.

System Health monitoring: A system monitoring module(admin) module(figure 10) is present which constantly hits the microservices rest API to monitor the health of these microservices. If notices the health of a module degrading it sends a notification to devops team.

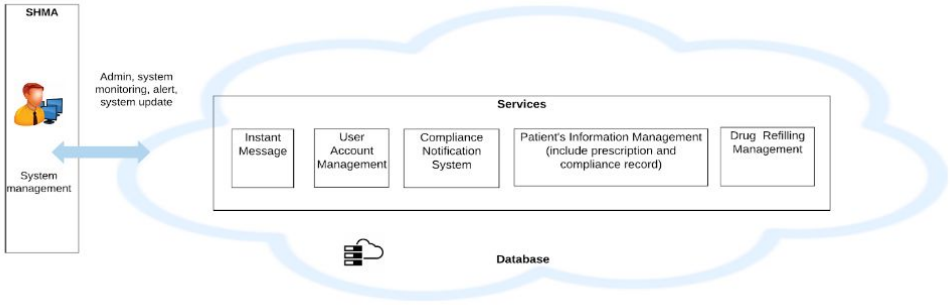


Figure. 10: Health Monitoring System

2.2 Software Architecture View

2.2.1 Block Diagram

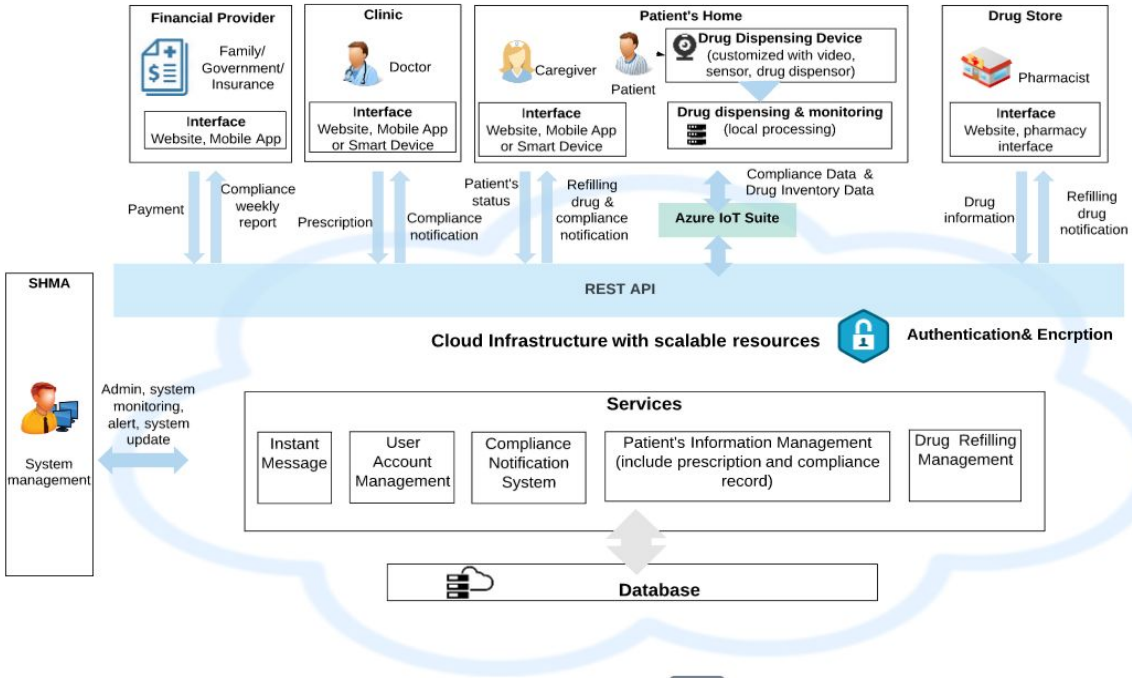


Figure 11: SHMA Block diagram

Key Blocks:

- **User Account Management**
  An external service, Azure Active Directory, is responsible for Managing account of different users include doctors, caregiver, pharmacy and financial provider. The patient can have a personal account if they are willing to use the interface and interact with the system.
- **Drug Dispensing Device:**
  A customized smart device which dispenses the drugs to the patient according to the prescription. When the patients take the drug, the monitoring camera on the dispensing device will record the patient's drug taking process and send the video data to the local processor.
  There is also a sensor which monitors the drug quantity in the dispenser on the device. When the drug supply is low in the dispenser, the sensor will send alert through local processor and cloud to the drug store to request refilling the drug/drugs.
- **Drug monitoring and processing unit**
  A local processor extracts and processes patients' drug-taking monitoring video and drug supply data from camera and sensor. It sends that data to Azure IoT Suite on the cloud.
- **Azure IoT Suite**
  Azure IoT Suite is a customizable module offered by Microsoft Azure which consist of a preconfigured IoT solution, which include device management, event

creation, event routing, processing and then calling other backend API. The system receives the patients' drug-taking compliance data sent from the local processor, converts to visualization records and updates the patients' drug taking history.

- **Patient Information Management:**
  An internal service that manages each patient's personal information, prescription records, and compliance records. The patients' caregivers or patients themselves can update their personal information including home address, life schedule, health conditions etc through the system.
  When doctors change the prescription for patients, the system will update the prescription and send notifications to the drug store, patients, and caregiver. The system will also change the schedule and instruction on the drug dispensing device and send reminder to patients and their caregivers according to the new prescription and schedule.
  When patients violate the prescription and skip taking drug/drugs certain times, the management system will send alert to Compliance Notification System to send an alert to the patients' caregivers and doctors.
- **Compliance Notification System:**
  An external notification service, Twilio, will send notifications (email, message, etc) to the patients' caregivers and doctors when getting an alert from Patient Information System. Usually, the alert got sent when patients skip taking drug/drugs certain times.
- **Drug Refilling Management:**
  An internal service that receives the drug supply data from the local processor when the drug supply is low. It sends a notification to the drug store for requesting refilling drugs.
- **Instant Message:**
  An external online chat service that offers real-time text transmission over the Internet between doctor, patient, caregiver and drug store.

2.3 Architectural Decisions and Rationale

2.3.1 Use cloud for deploying backend:

Since we are a small startup, we do not want to make a large initial investment in buying servers. Cloud is the most applicable infrastructure for since it allows us to use resources and pay as we utilize resources. It also allows us to scale up and down resources needed for the system based on the demand. Furthermore since our monetization model is subscription, our revenue is related to usage which then will be related to our cloud bills.

2.3.2 Local video processing:

Fat client and fat server. We have decided to process video to check if patient is compliant for his medication locally rather than sending video data to cloud. This will make sure that patients privacy is taken into consideration and no one can use the system to watch him, since the videos never leave his home. Furthermore we will save the cost of sending the bulking video data to cloud and then processing and

storing it. Furthermore having a local processing allows our system to be resilient, especially when their is an internet connection breakdown.

2.3.3 Client-server model:

Since there are multiple stakeholders in the system, there will be many requests which need to be addressed in real-time. Therefore, a client-server model is appropriate to use to fulfill the needs. There are different types of services to address different kinds of requests separately.

2.3.4 Layered architecture:

We have used layered architecture and have divided them into database, logic and presentation. We also have an additional layer where processing is happening on the client

2.3.5 Service Oriented architecture (SOA):

We have used SOA for backend services, which allows our architecture to be agile, modular and loosely coupled. This allows us to but external services and modules and integrate it in our system as need be.

2.3.6 RESTFUL API:

We also have decided to use RESTFUL API for our services, so that in future we can monetize our API. Furthermore, it also allows our client side coding to be flexible and deployable of different heterogeneous devices.

2.3.7 Event driven:

We have used event driven architectural style for processing data from local dispenser devices. It allows real time processing of the patient's drug compliance data. It also makes our system scalable and allows dispenser devices to be added as needed.

2.3.8 Authentication and encryption:

HTTPS and token - Since there are multiple stakeholders in the system with varied authority levels, the authentication and encryption are needed to ensure each party can use the designated features and access to data depends on the authorized level. We have decided to use HTTPS to encrypt communication between services and client. Furthermore, we will a user management module which will manage authentication and authorization for different users. Whenever user attempts to request different service, the user management service will be called. Based on the user id it will generate a token and used by the client to call other services.

2.3.9 NoSQL database:

NoSQL database allow flexibility(No strict schema) in storing data.Database is scalable and provide good performance for unstructured and semi-structured data.

2.4 Frameworks/Services:

2.4.1 Azure Cloud

Our team has decided on using Azure cloud since it is HIPAA compliant, which is a US government requirement when handling medical data. Furthermore it offers a lot of services which we need for our project. It offers Azure IoT suite which is the solution we will use for connecting, managing, processing and then creating events

from drug dispenser devices to our backend services. Azure is the leader in providing IoT specific services. We will also use Azure active directory as our user management module for user authentication and authorization. We will also use Azure App service for deploying our backend services which provides a git base continuous deployment tools. Azure App service further allows for monitoring of the web services and provides insight about the services usage. We will also use Azure CosmosDB which is there NoSQL database. CosmosDB allows us the ability to scale and replicate data for better performance. All of the Azure services which we are planning on using are HIPAA compliant. And since we do not store data at any other place, our complete product will be HIPAA compliant as well[5].

2.4.2 Twilio

We will use twilio for sending notifications and alerts. Twilio offers an API which allows alerts and notifications to be send to a number of different mediums like email, SMS and phone calls. It is very simple to integrate to our system

2.4.3 MAVEN+Springboot

We will use this framework for developing our backend services.

2.4.4 Alexa skills kit

We will use alexa skills kit to develop a skill (smart devices apps) for our product.

3. Development Strategy

3.1 Agile development strategy

For deploying we will use agile development strategy. Our first task will be to develop the Minimum viable product (MVP) (see Table1). Once the MVP is shipped we will start working in 2 weeks Sprint and keep adding next features based on our backlog(see 3.2). Backlog is ordered based on the importance of the feature, but that order might change when we get feedback from our customers.

Table 1. Minimum Viable Product

Deployment platform	Website
Services/Modules	Login service, patient information management, drug dispensing device, drug dispenser monitoring (IoT), Azure IoT suite
Platform	Azure
Backend	CosmosDB (Azure docDB)
Timeline	6 months

3.2 Backlog (Next Iterations):

1. Notification
2. System Management
3. Drug Refilling
4. Instant Messaging
5. Mobile App
6. Smart Devices
7. Water availability detecting sensor

4. References

[1] https://www.medminder.com

[2] https://www.pilldrill.com

[3] https://pillsy.com/

[4] https://adeliarisk.com/is-microsoft-azure-hipaa-compliant/

[5]https://docs.microsoft.com/en-us/azure/iot-suite/iot-suite-v1-what-are-preconfigured-solutions

5. Appendix

The appendix is the phase one project definition,“*Smart Home Medication Adherence*”.

Smart Home Medication Adherence

Project Proposal

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1. Introduction:

1.1 Background:

Medication nonadherence - Centers for Disease Control and Prevention (CDC) estimates that medication is not taken as prescribed 50 percent of the time. It is estimated that three out of four Americans do not take their medication as directed. So, patients don't take their medications as prescribed is a very common problem. The CDC estimates that non-adherence causes 30 to 50 percent of chronic disease treatment failures and 125,000 deaths per year in this country and costs the health care system nearly $300 billion a year in additional doctor visits, emergency department visits and hospitalizations.

There are many reasons why patients do not take medication as instructed. The most common one is they forget about it. They may forget to take it with them when they are going outside. Another reason is that patients generally lack knowledge about the drugs and why is it important for them. They may not be convinced of the medication's effectiveness or be unsure that it is working. They may fear the side effects or have difficulty taking the medication. They may misunderstand verbal instructions given by the doctor.

(References: https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm485545.htm, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/, https://wire.ama-assn.org/practice-management/8-reasons-patients-dont-take-their-medications)

1.2 Project Description:

We are developing a Smart Home Medication Adherence (SHMA) system which will solve the current medication nonadherence problem. Our system will provide the right medicine at the right time to the patient using a drug dispensing unit. The system will help the patients remember when medications are due by alerting the patients when it is time to take the drugs. It will also monitor patient's drug intake activity and send the patient's drug intake compliance records to a caregiver and doctor. The system will be able to connect doctor, patient, caregiver and drugstore. It will manage patient's prescribed medication and will be able to order for refills. This system

will also provide education to the patient about his prescribed drugs. Patients will be able to use the system to communicate with the caregiver and doctor if they have any concerns regarding medication.

1.3 Proposed Perspective:

We are a technology startup focused on developing a platform for prescription drug compliance system. We will sell subscription to customers which can monitor, if they are taking the right drugs at the right time. Our target customer base will be patients, their relatives, insurance companies and government who wants to make sure patient takes their prescription drugs on time.

2. Constraints

1) **Cost-** Hardware Cost (current available hardware cost $2000) +software development cost+ Service/Subscription cost (approximation)
2) **Timelines to release software** - The investors expect the system should be released within 2 years, and the MVP in 4 months and new features should be release every 2 months.
3) **Accessibility** - System only focuses on the patient's medication compliance at home.
4) **Drug usage monitor** - System monitors the use of drugs prescribed by the doctor only and cannot monitor un-prescribed drugs
5) **Hardware compatibility** - The functionality of the system is compatible by the current technology of the drug dispensing unit in the market
6) **Security** - The system is US government HIPAA (Health Insurance Portability and Accountability Act of 1996) compliance. It can only be used in the US.

7) **Follow compliance** - The system can record video for limited time(5mins) to determine if the user follows compliance or not and user must take the prescribed drug at the location where camera is implemented, or camera must be implemented at the location where it can capture the user compliance.

The patient is at risk of health compliance in certain situation:

a) If he/she does not take the pills in front of the camera.

b) Give medicine to someone else.

c) Throws the pills away.

d) Spit the medication.

3. Stakeholders

1) **Patients** - Person whom are system will monitor for prescription drugs compliance

2) **Doctor** - Person who will add/update the prescription in system.

3) **Caregiver** - Person who monitors if patient is complying with drug compliance and will answer their concerns, can be family member or nurse

4) **Patient dependent on financially -** Person/entity who will buy the system for the patient, can be a family member, insurance provider or government support.

5) **Drug store** - Will be responsible for refill of the drug dispenser based on doctor's prescription.

6) **System Admin** - Provides the customer support for 'how to do queries'.

7) **IT Admin** - Manages the technical tasks such as security updates, new features release etc.

4. Requirements

4.1 Functional Requirement - User Story

(Note: All the requirements listed below are based on the priority of importance.)

1) Patients

ID	As a /an	I want to	so that	Notes
1	Patient	Be able to get the right drug, at the right time and in right quantity.	I can follow doctor's advice	Solve it by using drug dispenser
2	Patient	When taking drugs, I expect the system to automatically monitor through a camera.	System can keep tracking of the patient's drug taking record	Video - Machine learning
3	Patient	Get alert on the specific time when I need to take drugs	I know it is the time to take drugs	
4	Patient	Have a clear instruction (which drug/drugs I should take each time I get alert, take the drug with meal or not, food restriction)	I have the knowledge to take the correct drugs at the right time	
5	Patient	If I am not able the refill the drug myself, I can get my drugs refilled by system	I don't have to worry about refilling of drugs	

6	Patient	Be able give feedback to doctor or other caregivers (eg. feeling uncomfortable etc)	I can communicate to doctor and caregiver	Voice interface
7	Patient	Get doctor's feedback about my health condition	I know my health condition	Voice interface
8	Patient	Get notified if doctor changes my prescription	I know if there is any update	
9	Patient	Get doctor's/caregiver advices about drugs I took on time in the past week	I know if I miss it or not	
10	Patient	Get the reminder to bring the water before taking the drugs	I can take drugs at dispenser	Camera monitoring time is limited

2) Doctor

ID	**As a /an**	**I want to**	**so that**	**Notes**
1	Doctor	Be able to login/register to the smart home medical adherence system	I can access to system to enter patient's prescription	

2	Doctor	I should be able to see the individual patient weekly report	I can check if they are taking the prescribed medication timely	
3	Doctor	I should be able to update the drugs prescription for patient.	I can change the treatment for patient based on health condition.	
4	Doctor	I should be able to add comments/advice if there are any concerns from patient about the prescription and should get alert if there is any query from patient/family member/caretaker.	I can add comment and feedback for family members/ caretaker on weekly report if required.	
5	Doctor	I should be able to link the particular hospital website patient record to this system	So that I can import the existing information and use the patient's record	
6	Doctor	Doctors should be able get the alert if the patient is not taking the medication as per prescription	I can request family members to pay attention.	
7	Doctor	I should be able to see the list of patients to whom I have prescribed medicines	I can monitor patients records	

8	Doctor	I should be able to update the patients records	If there are any additional personal details or information is to be added later, I should be able to do that	
9	Doctor	I should be able to see the list of the old patients based on requested time frame	I can see treatments of the old patient for whom treatment is completed.	
10	Doctor	I should be able to see while page load only ongoing treatment patients records	I can only see the ongoing treatments patients records	

3) Caregiver (family, nurse)

ID	**As a /an**	**I want to**	**so that**	**Notes**
1	Caregiver	Be able to login to the system and allowed access to the patient's drug taking information and records (eg. taking drugs at right time, right quantity, patient gets alert)	Patient gets monitored. I can track the patient's drug taking records	
2	Caregiver	Get alerts if the patients are not taking medication	I can follow up with the patient	

3	Caregiver	If patient need me to help with refilling drugs, I want get alerts when drugs are received and have authority to refill drug dispenser drugs	The dispenser can be refilled with drug on time	
4	Caregiver	Be able to provide knowledge in text/video/audio format to the patient about drugs via system	I can convey the importance and knowledge of taking medicine to the patient	
5	Caregiver	Add patients leaving home schedule in system	Patient gets a reminder before leaving home to carry the required drugs	
6	Caregiver	Be able to contact doctor	I can report anything he/she found to doctor	
7	Caregiver	Be able to get recommendations (i.e. best medicine schedule for patient) on my dashboard every month	It becomes easier for patient complies with drug intakes	Machine learning to recommend time
8	Caregiver	Be able to add/update patients drug intake schedule	Patient's schedule gets updated	

4)Patient dependent on financially (family, government, insurance)

ID	As a /an	I want to	so that	Notes
1	Provider	Access to the system (role-based authentication.)	I am able to see the drug finishing results of all the patients I provide financial support for	
2	Provider	Get consolidated report for all the patients I have bought this system for	To monitor if all patients are always complying with drug intake	
3	Provider	Look at the dashboard to see if the patient is taking drugs on time and right quantity	Patient are always complying with drug intake	
4	Provider	Make sure patient data is secure	It is HIPAA compliant	
5	Provider	Make sure patient is getting drugs delivered on time	Patient can take it on time	

5) Drug store (organization which refills drugs for patient)

II D	As a /an	I want to	so that	Notes

1	Drug store	Be able to view the doctor's prescription for each patient inside the system	I can refill the correct drug for the patient (put in a special case and send to the patient)	
2	Drug store	Be able to communicate with the patient	If patient need to consult how to use the drug, I can answer questions	
3	Drug store	If the patient can't refill the drug himself/herself and the patient doesn't have a caregiver, or the patient want the service that drug store refills the drug to the device, I can access the patient's home	I can refill drug to the device	
4	Drug store	Get alert when the drug is used out	I can refill drug(s) for patient	
5	Drug store	Be alert when doctor change the prescription	I can change the drug according to the prescription	
6	Drug store	Be able to be alert when the drug is destroyed or lost,	I can send the drug to the patient again	

		and the system and proved that		

6)Admin

ID	As a /an	I want to	so that	Notes
1	IT Admin	Get a system alerts when the system doesn't work as expected	I know when there is an issue before it is noticed by customers	
2	IT Admin	Be able to update the system (continuous improvement)	I can add new features	
3	IT Admin	Have access to the system and the troubleshooting guidelines	I can fix the issue	
4	System Admin	Set up new account for customer	I can help patients to start using the service for the first time.	
5	System Admin	Be able to view the patient's address and some additional information	I can use the information in emergency.	
6	IT Admin	Be able to get feedback/result about the system	I can propose next updates which needs to be made for the system	

7	IT Admin	View and analysis the data	I can perform data analysis and provide recommendations for the improvement of the system.	

4.2 Non-functional requirements(NF)

4.2.1 Availability (Service Level Agreement)

Ref:	**NF1**	**Title:**	**SLA (service level agreement) Requirements**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. Website availability is required to be 99.9% for external and internal web users. 2. In case if a complete system is down, the DR (Disaster Recovery) website will be available (Need to consider the cost) 3. Data backup frequency-Monthly 4. Maintenance outage is required to perform the upgrades and install patches of security software, updating the website data which should be clearly mentioned and agreed in SLA (service level agreement) document 5. System regularly should check the availability of the hardware in patient's home		
Notes	SLA agreement document must be prepared separately to agree on the SLA terms.		

4.2.2 Security

Ref:	**NF2**	**Title:**	**Security and Data protection**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. Different stakeholders (roles) have been identified with different business-related process in earlier section. The system will require to have role-based authentication and access control model in place. 2. System require to have user management facility such as add, delete, assign role, assign read/write/delete function to different users. 3. System requires to have proper HIPAA compliance authentication mechanism to store and retrieve patient's confidential data. 4. IT Admin will have JIT (just in time) based access to the production environment. Changes in production environment will be logged.		
Notes	N/A		

4.2.3 Portability

Ref:	**NF3**	**Title:**	**Portability**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		

Description:	1. The website is accessible on laptop/desktop, mobile, tablet platform. Mobile friendly version of website is required. 2. Website is required to have cross browser compatible. (Commonly used browsers such as Mozilla Firefox, Google Chrome, Edge, Opera, and Safari)
Notes	N/A

4.2.4 Performance

Ref:	**NF4**	**Title:**	**Performance**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. System should be able to scale up and scale down based on demand 2. System should be able to handle a maximum of active 1 million users and devices at a time 3. Website response time should always be less than 2 seconds.		
Notes	N/A		

4.2.5 Usability

Ref:	**NF5**	**Title:**	**Usability**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		

Description:	1. UX and UI should be intuitive, easy to use and designed based on human centric design 2. User interface for healthcare providers should be similar to currently used medical systems 3. Tutorials and "how to do" videos should be created to make it easier for customers to use the system 4. Website should be available in top 10 different languages 5. People with disabilities should be able to use the website
Notes	N/A

4.2.6 Testability

Ref:	**NF6**	**Title:**	**Testability**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. Automated end-to-end testing should be performed for all the main functionalities 2. Performance and system response test should be conducted in staging environment each time before system update is being made 3. Every feature should have unit test		
Notes	N/A		

4.2.7 Scalability

Ref:	**NF7**	**Title:**	**Scalability**

Owner (User):	SHMA Client (Insurance Company, Family, Government)
Description:	1.Total User Base:(assumption): Assume to increase by 10% every year. System should be able to support this growth. 2.Storage: System majorly stores the patient treatment and his compliance report. So, it required to store a minimum of 7 years or more (patients treatment could be for longer duration) of data including history of each patient. In future based on needs it can increased. 3.Platform: The application should be hosted on cloud. This would help and allow scaling the solution depending on the load with lower cost.
Notes	N/A

4.2.8 Agility

Ref:	**NF8**	**Title:**	**Agility**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. The system should be easy to support to different platform. 2. The system will be produced in short, reliable and low risk releases ensuring that it is in line with the user feedback and easy to shift with the business strategy and market requirements		
Notes	N/A		

4.2.9 Supportability

Ref:	**NF9**	**Title:**	**Supportability**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. Components must be able to run when disconnected from the central resource and can cache the settings locally for use only when disconnected. 2. A support model should be designed to debug problem 3. The system may use third party tools for improved supportability 4. A support manual should be provided for user.		
Notes	N/A		

4.2.10 Flexibility

Ref:	**NF10**	**Title:**	**Flexibility**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. The system should be compatible to work with other system and hardware. 2. The system should be designed such as new features can be added easily.		
Notes	N/A		

4.2.11 Applicable Standards

Ref:	**NF11**	**Title:**	**Applicable Standards**
Owner (User):	SHMA Client (Insurance Company, Family, Government)		
Description:	1. The system must follow the W3C web standards. 2. The system will conform to HIPAA. 3. The system should conform to the OPPA (Online Privacy Protection Act) laws.		
Notes	N/A		