Design of Cyber-Physical Interface for Automated Vital Signs Reading in Electronic Medical Records Systems

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Abstract— The focus of this project is to study the design of a cyber-physical interface for automated vital sign readings in Electronic Medical Record Systems. This is presented as a solution for a need in actual EMR systems where the reading of vital signs is done manually which is error prone and time consuming. The domain application knowledge and prototype used for the development of this paper is made possible with the collaboration of the Alliance of Chicago Community Health Center LLC.

Keywords—CPS, Electronic Medical Records, Sensors, Software Object Model, Vital Signs Readings, Meaningful Use.

I. INTRODUCTION

The basic goals of a medical record are to accurately reflect the course of an illness and indicate its probable cause [1].

In early 1960, academic and medical community tried to put patient medical records into a computer but they were not very successful [2]. Since then, the attempts to put medical records into electronic format continue. Nowadays, there exists a variety of vendors offering different products that hospitals, community centers, and private practices are starting to adopt.

Different from paper records, Electronic Medical Records (EMR) are systems where medical providers document encounters they have with patients electronically. Such system can bring many benefits such as providing flow sheets, care-alerts to clinicians, graphs, electronic prescription, decision support tools, and automatically generating reports and statistics.

However, the use of software technology in Healthcare is still far behind compared to other industries and there exist large room for improvement. One of the actions that the U.S. government has launched in order to reduce this gap, improve the quality of health care of the population, and the adoption of electronic medical records is the Meaningful Use incentive program.

The Meaningful Use incentive program provides a financial incentive for the meaningful use of certified EMR technology to achieve health and efficiency goals. Some of them include the use of certified EMR in a meaningful manner such as reading of vital signs of patients in all encounters, recording demographics (gender, race, ethnicity, date of birth, and preferred language), implementing drug-drug and drug-allergy interaction checks, e-prescribing, the electronic exchange of health information and providing clinical summaries for each office visit, among others [3].

II. APPLICATION DOMAIN

A. Definition of the Problem

As mentioned in the introduction, in order to provide a quality health care to the population and be part of the Meaningful Use program, the reading and storing structured data of vital signs of patients during all visits is a fixed requirement. According to [3]. The primary care physician enrolled in this program can meet this measure by taking the vital signs for every visit. Other specialists such as dermatologists, dentist, ophthalmologist, physiatrists and medical assistants, are required to do so as well.

Also physicians need to be able to document findings and search for information during the encounter in a quick and straightforward manner while using the electronic medical record. According to a research by the National Assembly on School-Based Health Care, the patient encounters last between 7 to10 minutes and usually 25% percent of the time is spent in documentation, which means physicians need to be able to record an encounter in less than 2 minutes [4].

Finally, the correct and accurate reading of vital signs of patients during encounters is crucial for the medical provider in order to do a correct assessment and make a correct treatment plan [9] during the visit.

The vital signs that need to be recorded are:

- Blood Pressure
- Temperature
- Pulse Heart rate
- Oxygen Saturation
- Height
- Weight
Unfortunately, reading and recording vital signs are performed manually. The basic workflow in which the reading of vital signs in EMR is performed is depicted in Fig. 1. Typically this process is done by a nurse practitioner or physician assistant using different devices that can be analog or digital. Some of the most commonly used devices for obtaining the readings are shown in Fig. 2. Every time a vital sign is read, the information is typed manually into a form and then recorded. In some cases paper notes are taken. Once all the vital signs are read, the medical provider arrives, logs-in into the EMR and opens the patient record to visualize all previous data, then documents more findings through the Chief Complaint and Review of Systems, and finally provides a treatment, prescription, or referral if applicable.

Some of the disadvantages of doing vital signs readings in this way include but are not limited to:

- **Time consuming.** In average during a normal day of work a provider requires to see a patient one every 15 minutes. The time available during a patient encounter is very limited.

- **Prone to inaccuracies or typing errors.** Reading from so many devices of different vendors and typing data manually under pressure of time is error prone.

**B. Problem statement**

The lack of automatic reading of vital signs in EMR systems is prone to errors and time consuming, and hence it can causees considerable impact toward the quality of healthcare of thousands of patients around the country in the actuality.

The objective of this paper is studying a solution based on the design of a cyber-physical interface that integrates sensors over a wired network which allows to retrieve and store information into EMR system as structure data.

**C. Current Software Architecture**

The current EMR system does not need to be replaced in order to satisfy the problem presented in this paper. As it will be discussed in the next section, the solution needs to be implemented over the existing system environment. However, it is of great importance to know the current software architecture in order to determine the best implementation.

The EMR system is a semi-closed system that allows the use of tools to modify elements and get data in and out of the system, but no core modifications are allowed. This is because we deal with a proprietary system and is licensed by a vendor (GE Healthcare). Typically the most common method to insert data is through the creation and use of forms and manipulation of variables. To retrieve data, the generation of reports is performed.

The current EMR System, which trademark is Centricity Practice Solution®, is deployed using a distributed architecture over a Citrix Server configuration. This becomes is relevant, since the data collection of vital signs needs to be done at clients PCs over this architecture.

![Figure 1. Normal workflow involving vital signs reading. Source: Survey at Alliance of Chicago Community Health Services, LLC](image-url)
The EMR System can be composed of one or more databases distributed over a network. It is the Citrix Server which provides services to the Client machines running the EMR. At the client side, the EMR application allows users to log-in with unique username and password, then search for the patient, do queries and display the data from the server. In order to start documenting and capturing the vital signs, an encounter type and the vital signs form must be selected. Each encounter type has many forms which collect specific medical data. Once the data is entered in the form, it is sent to the server, which saves the information of the patient records into specific variables known as obsterms (observation terms). The overall software architecture of the current EMR systems is shown in Fig. 3.

III. SOLUTION DOMAIN

A. Design Goals

The design goals are the qualities of the system that need to be prioritized and optimized.

The identification of the design goals can be done according to the different stakeholders involved in the entire EMR environment. They are also influenced by the non-functional requirements of desired the Cyber-Physical interface.

1) Client (Health Center): Low cost, increased productivity, flexibility, reliability, runtime efficiency, and compatibility with existing and future versions of the systems.

2) End User (Medical Staff): Safety, Functionality, user-friendliness, usability, ease of learning, fault tolerant, robustness, portability and good documentation.

3) Developer/Maintainer (Alliance of Chicago Staff): Minimum number of errors, reliability, portability, good documentation, modifiability, reusability, readability, adaptability, well-defined interfaces and elements.

In compliance of the nonfunctional requirements and problem statement, the Adapter Pattern is proposed as the most adequate solution.

B. Subsystem Decomposition

In order to reduce the complexity of the solution domain, the decomposition of the problem into simpler parts is suggested. The goal is to decompose the system into relatively independent subsystems allowing concurrent teams to work on individual subsystems with minimal communication overhead.

Based in the functional requirements and adapter pattern approach, the prototype developed is integrated by the following elements:

- EMR (Current System)
- Data Handler (Software Adapter)
- Vital Signs Reading Station (Hardware Topology)
- Customized Vital Signs Form

A graphical representation of the initial subsystem decomposition using the three-tier architecture is presented in Fig. 4. Three subsystems (layers) can be identified: Interface, Application and Data.

The complete subsystem decomposition is designed containing subsystems that are loosely coupled, so modifications to one of the subsystems will have little impact on others, which minimizes the impact of errors or future changes that one subsystem have on other subsystems. In the same way, this decomposition has high cohesion, because each subsystem contains many related objects that perform similar tasks.

As explained before, due to the nature of the vendor system, the functional and non-functional requirements, this subsystem decomposition contemplates the use of an adapter located between the application tier and data tier. This guarantees compatibility with the existing and future versions of the system; other benefits include flexibility, reliability, modifiability, reusability and low cost production.
Applying the three-tier architectural style, the subsystem is decomposed in three tiers:

- **Interface Layer**: it includes all boundary objects that deal with the user, including a Customized Vital Signs Form and the Reading Station containing the interconnected sensors.

- **Application Logic Layer**: it includes the control object which realizes the data collection from the Vital Signs Reading Station, then display the information in the form and also processes the data and sends it to the data layer using an adapter.

- **Data Layer**: it denotes the existing EMR system without any modification. Its functionality is based on the selection and use of encounter types that load different forms including the vital signs form to realize the reading and storage of the information. The access to this layer is done using an adapter.

The complete subsystem decomposition is displayed in Fig. 5 including the subsystems and their corresponding objects. The Vital Signs Reading Station used is Welch Allyn Spot Vital Signs® LXI. It features will be explained in detail in the hardware/software mapping section.

### C. Concurrency

According to previous discussions, the current EMR system is a multiuser environment that works over a Citrix Server deployment, such a system won’t be modified. The current approach is based in Three-Tier architecture with an adapter pattern which will enable two interfaces: a customized vital signs form and the vital signs reading station containing the sensors inputs, and an application control module.

From the point of view of the current EMR, no apparent change will be done, since the adapter will help us to retrieve and display data in a new customized vital signs form, and instead of using the keyboard to input the data, it will be done through the reading station using the sensors.

These two interface elements (Customized Vital Sign Form and Reading Station) will be treated as a single user environment, making the assumption that the multi user authentication and control access has been performed in the lower layers (Application Logic and Data Tier). This approach decreases the coupling of the system.

In order to increase the functionality and reliability of the system, the customized vital signs form can be executed independently from the vital signs reading station. This is important in the case that the network connectivity or sensors of the reading station fail or become unavailable. The option to type the vital signs manually using a keyboard into the form will be always available.

The adapter will be plugged between the customized vital signs form and the current the system. The objects of the Interface and Application tiers can only process a single event request of vital signs reading at the time and no parallel processing is necessary due all processing is sequential. The detailed dynamic behavior of the cyber-physical interface for vital signs reading implemented in the current EMR system will be explained in detail in the use cases of the Boundary Conditions section.

### D. Hardware/Software Mapping

The solution approach for the automated reading of vital signs is based on both hardware and software solution. In this section the corresponding mapping of objects onto the chosen hardware and software is explained. Also the hardware requirements, trade-offs, allocation and connectivity (dependencies) among components of this cyber-physical interface for automated vital signs reading is discussed.

1) **Mapping Objects into Hardware**: The mapping of objects is classified as follows.

   a) **Control Objects**: Data Handler Adapter, application installed at each Citrix Server. This application is in charge of retrieving the data from the reading station, data is then stored.
in a file at the Citrix Server and finally set to populate the form.

b) Entity Objects: Existing EMR System, Citrix Servers and existing databases. No changes to this object were made since the solution is based on an adapter pattern.

c) Boundary Objects: Custom Vital Signs Form visualized at the client workstations (supported by the Citrix server) and Vital Signs Reading Station physically connected using a wired connection (USB 2.0 or Serial Cable). These object are the interfaces in which the user with interact during the vital signs reading process.

It is important to highlight that each of these elements is located in different hardware devices and highly depends on the access to the Internet and the local wired connection between the Vital Signs Reading Station and client workstations (this can be appreciated in Figures 3 and 5).

2) Model of Hardware: For the model of hardware, many options were considered including the functional requirements and constraints including the dilemma between building or buying the hardware solution.

The adopted approach is based on buying an existing multi vital signs reading station that is available in the market. The advantage of installing a product that is already available in the market was selected considering that the product should meet the high industry standards in health care and reduce the changes in the workflow. Also the fact that an existing product is in the market, it means that has been already tested by the manufacturer and this reduces the development time of this project significantly and increases reliability.

This reading station Spot Vital Signs LXI® manufactured by Welch Allyn® was selected because it allows the reading of multiple vital signs including: blood pressure, pulse heart rate, oxygen saturation via pulse oximeter, and temperature with additional capabilities to enter height and weight directly into the device. This device was selecting considering its response time, cost and connectivity features. For a full list of its specification, the manufacturer website can be visited [5].

However, after exhaustive testing and exploration of this device, the conclusion of discarding automatic reading of height and weight was made. This decision was made considering that originally, this device does not provide the appropriate sensors, however additional equipment can de adapted in the future.

The Model of Hardware providing identification, distribution and connectivity of nodes and their corresponding objects is displayed in Figure 6.

E. Data Management

The data structure implemented in this approach is basically the same data structure used in the existing EMR. The vital signs data is stored in variables denominated observation terms, technically known as obstems. There is more than one obstem related to each single vital sign. Deciding the obstem in which the value of a vital sign will be stored is a decision to be made by the clinical team of each Health Center in which the system is implemented. For the purposes of study, in this paper, we assume that only one obstem to a vital sign is done. However, this can be modified eventually in the Data Handler Adapter, which at the end of the day, makes of this system more adaptable, reusable and customizable to the needs of each health center.

As indicated in Fig. 5, the vital signs reading station has a variable that corresponds to the value of each vital sign that has been read and saved. Each variable can be retrieved by invoking a method in the Data Handler Adapter that will transfer the data from the Welch Allyn® device to the Vital Signs form in their corresponding fields at the workstation. Once the form is saved, the data is transferred to the EMR and saved into the database in their corresponding obstems. In other words, the process of getting the data from the form to the EMR database is done the exactly same way as it would be if the data was entered using the keyboard, the only difference is that the data handler pulls the data from the machine and populates the form. This approach is also useful to handle exceptions and data corruptions, satisfying the non functional requirement of reliability, and runtime efficiency and fault tolerance.

F. Global Resource Handling

The access to the cyber-physical interface is already controlled by the existing policies of the system and varies from one health center to another, no new changes are necessary. Usually a role-based access control is implemented in which the permissions are granted based on the roles that individual user have as part of the organization. These roles include doctors, nurses, receptionist, and others. The use of the system is restricted to authorized users only.

The access can be granted and revoked easily in Centricity Practice Solution (EMR) by a super user. Usually permissions are assigned to a specific role (group of users) which reduces the need of updating permissions for every single individual. This also is extremely useful for user with multiple roles and keeping a consistent global control access.

The Alliance of Chicago suggests access control guidelines to the more than 30 Health Centers that serve across the country in order to protect the privacy and integrity of information of the patients. Also, is important to mention that in the U.S., the health information of persons is protected by the Health Insurance Portability and Accountability Act (HIPAA). Each of the health centers members of the Alliance
of Chicago are in compliance with HIPPA, as well with the “least privilege access” requirement by Role Based Access Control (RBAC) which suggests granting the minimum privileges required for individuals to perform their job functions.

G. Software Control

The software control of this cyber-physical interface is possible using the following application components:

1) Custom Vital Signs Form. This form is a slightly different new version of the traditional Vital Signs Form. It has been optimized so that allows the automatic reading of vital signs using the Welch Allyn® reading station. This form also allows inserting the data manually using the keyboard in case the Welch Allyn® machine fails or becomes unavailable. This form also has methods that allow the transfer of the vital signs data to the EMR System.

2) Vital Signs Reading Station embedded application. The vital signs reading station is a Spot Vital Signs LXi® model that has an embedded application that scan the vital signs from all the sensors. The person using this device can opt for using a specific sensor to read a single vital sign or all the sensors simultaneously depending of his needs. This application will read the vital signs and then store the information in the internal memory of the device.

3) Data Handler Adapter Application. This application is developed using the Device Connectivity Software Developer Kit [6] in order to transfer the information gathered and saved by the reading station to the client workstation and insert it in the customized vital signs form into their corresponded fields. As explained in the previous section, this transfer is performed using a serial connection. This application also provides handling of errors and integrity checking of the data transferred.

4) EMR System. This is the existing system denominated Centricity Practice Solution® developed by GE Healthcare® [7]. No major modifications are required; the only change is the redirection to the new custom vital signs form. The entire process of selection of an encounter type, opening the vital signs form and gathering of the vital signs from the sensors, as well as populating the form and saving the data to the Database into obstetrics is completely transparent due the use of the adapter application.

H. Boundary Conditions

In order to have a better understanding of the dynamic behavior of the solution approach presented in this paper, the description and exemplification of the initialization, execution of vital signs reading, termination and failure (exception handling issues) of the Electronic Medical Record system using the cyber-physical interface for automated reading of vital signs are presented in this section.

1) Initialization: The process starts when the user selects an encounter type (Office Visit) containing the Customized Vital Signs Form. Please note that an encounter type may have more than one form. In the particular case of the office visit encounter, the vital signs form is the first form to be loaded. Each time a form is closed, the option to load a next form or put the document in a specific status (hold, signed, discarded) is possible. Once the user has selected the desired encounter type, the system loads the obstetrics form database by doing a query. Then, the form is displayed into the screen by the Initialize ( ) method, allowing the new data to be entered into the fields by using the automated vital signs reading and/or manually. As it will be explained later in the discussion section, the option of allowing the data to be entered manually and/or automated was made by trying to minimize changes in the workflow. The sequence diagram showing the initialization process is shown in Fig. 7.

![Sequence Diagram](image-url)

Figure 6. Model of Hardware (allocation of components and dependencies) represented by a UML Deployment Diagram.

2) Vital Signs Reading Execution: After the custom vital signs form has been loaded, the user can start using it. When the automatic reading of vital signs is executed, it triggers the Data Handler Adapter, which communicates with the Vital Signs Reading Station (Welch Allyn® device). The machine starts reading the inputs from the different sensors and saves it into its memory. As soon as this process finish, the adapter
copies the values from the machine to the form, auto-populating the form in their corresponding fields. Once the data is pulled into the form, it is saved; no other action is required [8]. The sequence diagram showing the initialization process is shown in Fig. 8.

3) **Termination:** The user can decide to finish the vital signs reading by pressing “next” (load next form in the Encounter Type) or “close” button in the form. Upon selection of any of these options, the form is closed and the software control goes to the encounter type. From here the user can select another form or close the patient medical record. During the closing process of the Custom Vital Signs form, no data needs to be saved since it was previously pulled and saved by the “Get Welch Allyn Vitals” button. The sequence diagram showing the termination process when the “close” button is pressed is shown in Fig. 9.

4) **Failure:** Failure can be detected and handled in two different ways. The first one is considering that the failure happens in the reading station. The most typical error is that the sensor could not read one or more vital sign properly. In that case, the machine saves only the data obtained, omitting the rest. A message on the LCD screen of the machine will be displayed indicating the sensor(s) that didn’t receive any input. The decision of repeating the reading needs to be made by the nurse or medical assistant. The other possible failure is that the data cannot be transferred from the machine to the form. The possible causes can be a connectivity error or data loss. The Data Handler Adapter has the capability of detecting both situations and display an error message in the form. Then the nurse or medical assistant can decide between repeating the automated reading or inserting the data manually using the keyboard. The sequence diagram showing the exceptional cases detected and how are handled by the Data Handler Adapter are shown in Fig. 10.

5) **Complete process in normal behavior:** A complete sequence diagram presenting a normal behavior (without failures) of the entire system is shown in Fig. 11. This process as well as the four mentioned above makes the assumption that the user has started the EMR Application (Centricity Practice Solution®) and correctly logged-in.

6) **Custom Vital Signs Form:** As mentioned before, a customized version of the vital signs form was designed in order to adapt the functionality of automated vital signs reading. The development of this form should minimize changes in the workflow and be very user friendly. A screenshot of the proposed form is shown in Fig. 12.

IV. **DISCUSSION**

The proposed design of a cyber-physical interface prototype for automated vital signs reading was based on the functional and non-functional requirements presented in this paper. However, the main factor in which this solution was based, was to ensure that the vital signs data could be accurately obtained so that the medical staff provides optimal care to the patient. In order to achieve this, minimum changes to the nurse visit workflow were necessary. According to [6] once the integration solution can be implemented and tested, the new workflow needs to be agreed with the health center and medical staff. Then a proper training can occur to ensure knowledge transfer and standardization of the workflow.
In Fig. 13 the new nurse visit workflow in detail is shown. The process starts when the nurse arrives to the room where the patient is waiting. The nurse (or medical assistant) then logs-in into the existing EMR system (Centricity Practice Solution®) and opens an encounter type that contains a vital signs form. For purposes of this example, we make the assumption that the office visit encounter type was selected. After this the patient received indications to take a seat at the reading station and the nurse connects the sensors (oral thermometer, finger oximeter/pulse reader, blood pressure cuff) to the patient. Now the nurse clicks a button on the machine to enable blood pressure reading (required for this hardware model) and then presses “Get Welch Allyn Vitals” in the Customized Vital Signs Form. Once the data is transferred to the form, the nurse can proceeded to unplug the sensors and measure high and weight separately and enter this data manually.

The reason why the automated reading of height and weight was not implemented is because this would increase the cost considerably. It is important to remember that the medical centers in which this prototype will be implemented are community health centers that provide health care to...
medically indigent and uninsured people [8] and the economic resources that possess are very limited. However, this feature can be implemented by purchasing additional equipment or selecting a most advanced model from the vendor and modifying the data Handler Adapter. The fact that the interest for implementing state of the art technology to vital signs reading in ambulatory patient from the Alliance of Chicago, gives a clear vision of the imminence interest that this organization and the medical community has for the improvement of the health care of people. According to existing literature, most of the reading of vital signs is used for monitoring in non ambulatory patients. In other words, this project opens many doors for many improvements and research opportunities.

A. Advantages

The benefits and advantages that this cyber-physical interface provides not only impact the Nurse Visit workflow but also influence higher levels of healthcare. Some of them include:

- Considerable time reduction during patient encounter; [8] performed a study measuring the time using a traditional vital signs reading versus automated reading finding considerable time reduction in the process.
- Failure detection and handling during reading process.
- Minimum changes in workflow and current system.
- Less probability of error during vital signs reading. In [9] provides findings that between 10 and 25 percent of all transcribed readings include some type of error, which can lead to risks to the patients.
- Avoid duplicate vital signs readings.
- Improve safety, security and monitoring of patients.
- Provide important diagnosis ability. Example: hypertension [10].
- Overall improvement of quality of healthcare (the saved time can be used in other parts of the encounter like physical exam or treatment; also medical providers can see more patients per day).

B. Disadvantages

Every project has drawbacks and this is not the exception. Some of them include:

- Height and Weight still need to be entered manually, additional equipment can be purchased for this purposes (weight measurement can be implemented by connecting the Spot Vital Sings LXi to a different professional scales [11]).
- Maintenance requirement are slightly increased.
- Training is required to all medical staff that uses this form in order to make them aware of the new capabilities.
- There is always a learning curve that impacts medical staff productivity for the first couple of months after implementation.
V. CONCLUSION

The presented project focuses on the design of a cyber-physical interface for ambulatory patients as a method to get accurate vital signs readings. This data is treated as inputs and saved as structure data in an existing electronic medical record. It was demonstrated that this contributes to satisfy Meaningful Use criteria and improvement of health care of thousands of people.

This paper is a system design document (SSD) where the cyber-physical approach is discussed and decomposed using three-tier architecture. In this architecture the components are classified in layers that are independent of the other layers and depend only on the components in the next layer down. The main advantage of this approach is that the components can be modified without effecting components in the other layers. The interface layer contains the components that are necessary for viewing the application, the application logic layer contains the components that implement the business logic, and the data layer coordinates the connections to the databases.

During the design process, the trade-offs among the non functional requirements determined the final outcome. The initial conception of this project was to automate the reading of height and weight, but due that this would increment the production cost, the option was discarded. However, this leaves a door open for future improvement since this prototype is easily scalable. Another trade-off was presented evaluating impact that this approach would cause in the existing workflow. The decision to do the minimum changes was made considering that the goal was to increase productive with runtime efficiency and not the opposite.

According to preliminary tests and research [8], the average time that this cyber-physical interface for automated vital signs readings in electronic medical records can save per encounter is up to 2 minutes, which means a significant time reduction up to 20% of a regular encounter type. So, it can be concluded that the present project has a strong impact in the efficiency of the time of medical staff, which at the end of the day is reflected in better health care.

A. Future Improvement Opportunities

- The storage of vital signs of patients can lead to the analysis of data in order to identify public health related issues in the population such as obesity.
- Sensors over a wireless network can lead to telemedicine.

ACKNOWLEDGMENT

I would like to thank The Alliance of Chicago Health Services for giving me the opportunity to gain a strong knowledge of the application and solution domain through their EMR system; and the study of their medical device integration project. I would especially like to express my gratitude to my internship mentors, Shannon Pohl and Mary Kay Herman, and the community of health centers which they serve. I also want to thank J. Preston Taub whose English editing skills were of great help while writing this paper. My work is in part supported by NSF grants CNS 1018731, CNS 0746643, and CNS 1035894.

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