TELEDIAGNOSIS for COVID 19

SUMMARY OF THE PROPOSAL

Aim: The reduction of unnecessary visits to health care facilities and of physical direct exposure of doctors and patients, in an effort to reduce COVID 19 transmission, by supporting clinical examination and patient monitoring through a dedicated telediagnosis platform allowing complete tele-examination and reliable tele-monitoring.

Proposal: The development of an electronic health record with clinical decision support features, which will allow secure video conference (teleconsultation) supported by real time vital signs tele-monitoring (transcutaneous saturation, blood pressure, pulses) and tele-examination (digital stethoscope-remote auscultation). Availability of telemedical kits (mobile devices with appropriate peripherals for tele-examination/monitoring), which will be available to mild-moderate symptomatic COVID-19 patients followed in home or in hospital wards. Sustainability of the proposal, which can be adapted according to specific needs, as a secure platform for telemedicine purposes based on national priorities and needs.

A. INTRODUCTION

<u>History and challenges of bedside clinical examination in the era of Covid 19 pandemic.</u>

More than 200 years ago (2016) René-Théophile-Hyacinthe Laennec, a French physician revolutionized physical evaluation by replacing “direct” with “mediate” auscultation” as founder of the stethoscope [1]. However, chest auscultation still requires close physical contact of physician and patient with transmittable diseases representing a risk for both. Indeed, the founder of modern auscultation would eventually die ten years later from tuberculosis [2]. **In the current era of COVID-19** pandemic, where a disproportionate health and life loss of physicians among patients and victims is observed, **the established praxis for performing complete physical examination by direct physical contact should be reconsidered** [3,4]. Auscultation and physical examination remains an integral part of complete patient assessment, however “classic” auscultation and bedside examination **should be replaced by “tele”-auscultation and “tele”-diagnosis, for keeping the benefits and eliminating the risks of direct physical patient-doctor contact**.

<u>Tele-examination and tele-monitoring is needed for reliable telediagnosis</u>

Telemedicine can substantially support and change the modern medical praxis, in several settings including epidemics [5]. This is especially true in COVID-19 era, where physical contact should be strictly avoided. Based on recent experience and guidelines, the population exposure to COVID-19 can be confirmed by appropriate laboratory tests [6]. However, the resulting COVID-19 disease (including pneumonia, ARDS) and its severity is diagnosed based on history, symptoms reported by patient and physical examination by physicians, which precedes any decision for hospital admission or home follow up. The severity level of the disease can be assessed either based only by patient reporting symptoms, or by direct physical examination of patients (when reporting more severe symptoms) assisted by objective measures of cardiorespiratory status (vital signs, blood pressure, transcutaneous saturation being on first line). Telemedicine can support COVID 19 epidemic health care policies, by dedicated health records and platforms with decision support systems [7], triage systems, videoconference and teleconsultation [8], effectively supporting asymptomatic or mild symptomatic patients while reducing the need for unjustified visits to health facilities and virus spreading [9]. **However, the greatest benefit from telemedicine would be expected if it proves capable to eliminate the need for direct doctor-patient based physical examination by incorporating real time, reliable and confidential remote tele-examination and monitoring features**. This would **best serve moderate symptomatic patients** needing evaluation in health facilities and either is decided they **should be either monitored at home** or **inpatients**, in both cases **reducing to a minimum the physical contact with health personnel** [5].

There is an urgent need therefore to use telemonitoring devices incorporated within teleconsultation platforms, allowing objective assessment of patent's clinical status [2]. **Peripheral telemonitoring devices should be appropriately selected** for monitoring respiratory patients, including reliable **pulse oximetry devices** and respiration monitors. The remote validation (tele-auscultation) of chest sounds, although technically feasible by means of **digital stethoscopes or appropriate microphones** [10], is by far more challenging and subjective. Although chest auscultation by an expert physician provides important diagnostic information regarding the cause of dyspnea in any patient (heart failure associated with gallop rhythm, pulmonary hypertension with loud second heart sound, small airway obstruction associated with wheezing, alveolar disease associated with fine crackles etc), their interpretation can always be subjective based on physicians' expertise but also to technical properties of digital stethoscopes, transmission quality and reproduction devices used. **Automated computer-based diagnosis** has been applied with variable degrees of success both regarding heart [11] as well as chest sounds [12]. The incorporation of automated sound classification algorithms on teleconsultation platforms, supporting auscultatory finding objective (or continuous) interpretation would be a further development improving clinical performance of telemedical application.

<u>The need for multidisciplinary teams and establishment of national priorities in telemedical applications for Covid-19 pandemic.</u>

There is an urgent need for **multidisciplinary teams**, with **active participation of clinically active health care personnel to establish clinical priorities** and features that telediagnosis systems should have, test their performance in praxis and **support their use and promote their legalization** in countries where national rules addressing telemedicine are not established**, including Greece, (where telemedicine could be offered only by public hospitals so far** [13]**. The geographic distribution of the population in countries as Greece,** with limited access to tertiary health services supports further the urgent need for tele-examination and tele-diagnosis.

<u>Offering telediagnosis to the community</u>

Telemedical kits should be evaluated, enabling secure videoconference, with **carefully selected integrated peripheral devices**, proven quality in their performance allowing for complete tele-examination. **Selected Telemedical Kits should be distributed to the community and hospitals** for patients facing mild-moderate symptoms for their safe telemonitoring at home or in hospitals.

<u>Open infrastructure</u>

Finally, as pandemics are reminders how equal and fragile we are all standing in front of sickness and death regardless of ethnicity, religion or economic status, any research and investments in telemedical applications to support health care needs related to COVID-19 epidemic, including tele-examination and monitoring should be guided by an intention to **develop open infrastructure under open source licenses**, which should be distributed and shared for the global common well.

Telediagnosis not only for COVID-19 epidemic-sustainability of the proposal

Provided the highest priority of health services to early diagnosis and treatment of COVID-19 cases, it is to be expected that the regular care of the majority of chronic patients with diseases associated with considerable morbidity and mortality if not appropriate treated will deteriorate. Furthermore, there is an overlap of clinical presentation of more common diseases (such as asthma exaggeration, other respiratory infections) with COVID-19 clinical findings. The availability of secure and reliable telediagnosis can also serve the needs of non-COVID 19 patients. The telediagnosis platform and telemedical kits can serve the general population health needs also following the epidemic, offering high quality teleconsultation to populations with limited access to health services, due to geographical restrictions.

B. TELEDIAGNOSIS' GROUP PROPOSAL STEP-BY-STEP

1st step. Development of a designated telediagnosis platform for secure video teleconsultation, supporting tele-examination and tele-monitoring (pulse oximetry, electrocardiography, blood pressure measurement and digital stethoscope). In the Appendix you can find a technical approach for the indicative implementation of such an ecosystem able to provide telemedicine services to self-quarantined patients. It is based on the integration of available open source modules, so the total framework is easily customizable and extendable at low cost. More important, it is based on standardized protocols for medical information exchange (i.e. HL7, FHIR), so it is interoperable with all standards-based healthcare systems and medical equipment. This proposal is in line with the principles described in this document and is based on the available experience in our team from preceding deployments for research purposes [14]. This proposal could contribute a basis for further elaboration and development in case that our participation is positively evaluated for discussion at a second round of the competition.

2nd step. Validation - development of monitoring devices. 1st phase. Literature review and selection of the best performing peripherals (monitors, sensors, stethoscopes, pulse oxymeters), taking into consideration the reusability following disinfection, price and availability. 2nd phase. Design from scratch of new peripherals. Collecting feedback of patients and physicians regarding satisfaction with the equipment.

3rd step. Development of telediagnosis kits (mobile devices with platform installed and peripherals for tele-monitoring), which can be distributed and reused (following disinfection) to mild-moderate symptomatic outpatients, or symptomatic inpatients, allowing for secure, remote tele-examination of patients, early recognition of outpatients with need for hospital care and of inpatients with deteriorating clinical status.

C. OUR TEAM

Our team represents a multidisciplinary group of scientists which share the vision to offer open source material, supporting well established health care needs. The team leaders are first line clinically active academic health care professionals (Faculty of Medicine, University of Crete), with deep insight and knowledge of the needs of their patients, including Pediatrics, Pulmonology, and Social Medicine. There is a longstanding cooperation with group acknowledged scientists in Computer Science Department of University of Crete, with expertise in sound signal analysis, and in Department of Electrical and Computer Engineering of Hellenic Mediterranean University, with expertise in Internet of Things and Expert Systems. The team has prior expertise, phD Thesis support and publications in medicine, including epidemiology, infectious diseases, pulmonology as well as telemedical applications including electronic health records with decision support tools, digital phonocardiography for diagnostic and teaching purposes, automated computer analysis of heart sounds, design and application of primary health care services, development of open code software and hardware, networking, etc. Our team is open to any new members with expertise to the field of the proposal, welcoming any new idea or constructive criticism.

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APPENDIX

A proposed ecosystem for telemedicine services to self-quarantined patients

In the present circumstances of COVID-19 pandemic a very high number of patients with not critical symptoms is advised to stay at home in self-quarantine conditions for a period of at least 14 days. During this period the patient is required to follow doctors' instructions for monitoring his physical condition (e.g. by measuring his body temperature at least twice a day and self-examining other vital functions such as dyspnea), so when his situation get worse to be transferred to the hospital for hospitalization. At this stressful period of self-quarantine, the patient preserves less communication with his doctor or the nursing staff, thus increasing his sense of insecurity.

Our proposal attempts to facilitate exactly the nursing and health care of patients staying at home in a situation of self-quarantine. We propose the creation of a virtual hospital exactly for providing telemedicine services and keeping medical records for these patients. Each regional health directorate can deploy such a virtual health-care system for facilitating the provision of telemedicine services to self-quarantined patients and enabling their tactical communication with medical or nursery staff. A similar system especially for remote Electrocardiogram (ECG) analysis had been proposed and developed by our team in [1]. The proposed here virtual hospital's system for telemedicine and online monitoring of medical records should comprises two critical subsystems: The Electronic Medical Record (EMR) System for storing different types of medical data for the self-quarantined patients and a teleconferencing system for the live communication of the self-quarantined patients with the medical staff. In order the proposed system to allow its fast adoption by large communities it is required to be low-cost and exempted by any commercial licenses. The use of open source technologies to this end is a monodrome.

OpenMRS is an electronic medical record system (EMR) that established in 2004 to provide healthcare in developing countries [2]. The system has evolved into a medical informatics platform that is used all over the world to provide healthcare and avoid wasting of time and money providing effective cure and prevention. Very recently, on 6 April 2020, was released its Reference Application 2.10.0, which underlines that it is an alive and vivid framework. OpenMRS is an open-source project, based on standardized protocols for medical information exchange, such as FHIR and HL7, which with a compilation of other open-source projects or mobile phone applications can be extended or modified. OpenMRS satisfies functionalities such as patient registration and insertion of clinical notes to the system. In addition, there are no specific hardware requirements [3] and a dedicated implementers Wiki and forum by experienced members assists new developers or implementers [4]. Furthermore, it is compatible with mobile devices such as the SANA platform, which allows users to send medical data that the doctors can view, make a diagnosis and add a medication using a simple mobile phone [5]. SANA is an open source telehealth platform that was developed by MIT (Massachusetts Institute of Technology) to provide health care facilities in remote areas and increase the quality of care. SANA uses OpenMRS for data storage and supports connectivity with mobile devices. Users (e.g. the patient itself, a doctor or nursing staff) can collect medical data via the SANA mobile app and these data are sent to OpenMRS where doctors can view and make a diagnosis. SANA supports thus remote patient monitoring and decision making [6].

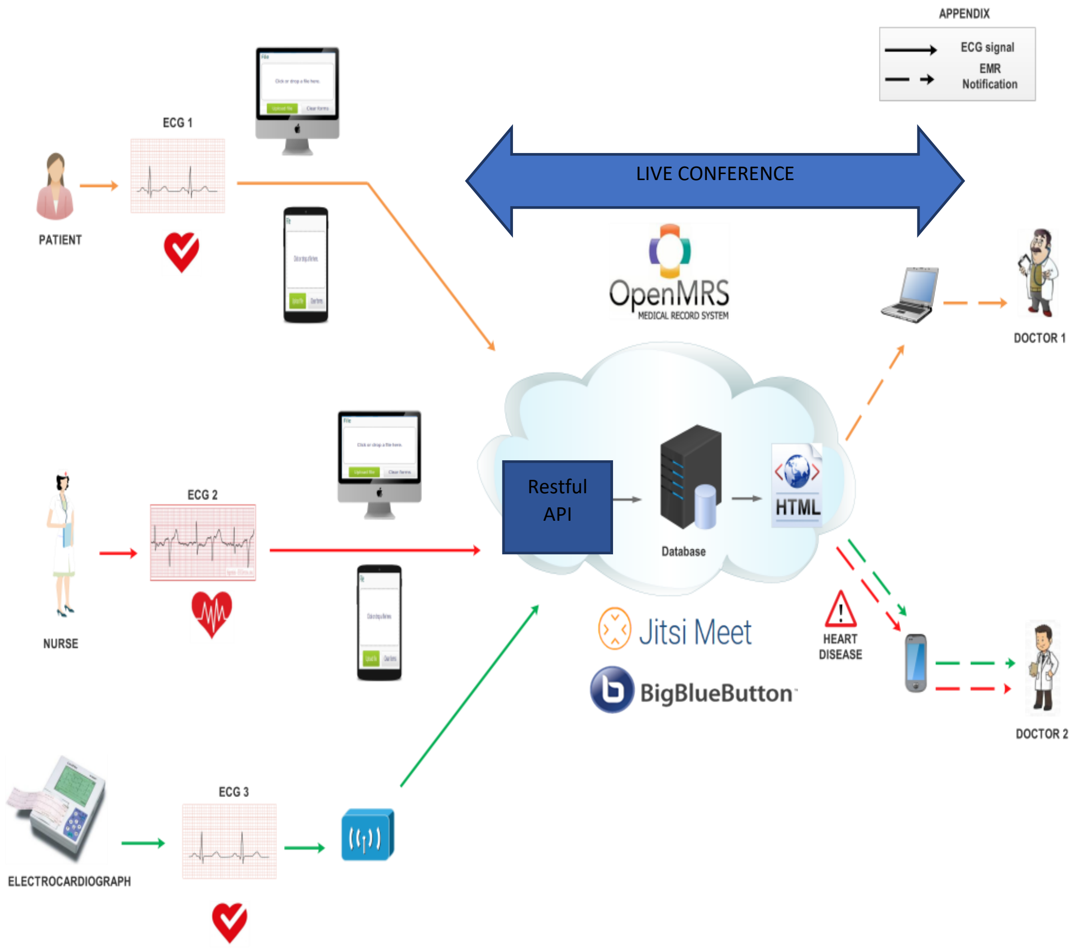

Figure 1. The proposed ecosystem for telemedicine services to self-quarantined patients

On the other hand, Jitsi Meet [7] and BigBlueButton [8] are fully encrypted, 100% open source video conferencing and chat solutions that someone can use for free. Both enable desktop or window sharing, invitation of users to a conference via a simple, custom URL, collaborative editing of documents, etc. In parallel, they enable LDAP Authentication, so controlled access to conferencing services is provided. Our team has deep experience with the provision of teleconference services to large audience using this software, hence we could easily support such a deployment for medical use.

Our proposal, here, includes the integration of SANA/OpenMRS with Jitsi Meet so a complete open source, but standardized, ecosystem for telemedicine services is provided to self-quarantined patients. Figure 1 illustrates the proposed system architecture for the creation of such virtual hospitals.

According to the proposed functionality, -quarantine patient, who has granted with access to the OpenMRS platform, uploads his biometric values (e.g. body temperature, SpO2 values, an electrocardiogram file and a stethoscope file) or other health information on the platform, as many times per day as the doctor has advised him. To this end, he can use his mobile device or any browser platform since the OpenMRS platform is accessible via a restful web application. For uploading biometric files, such as an Electrocardiogram (ECG) file for example, a specific HTML module that is called Visit Documents Module should be used. The user is navigated into the web application and uploads a compressed folder to the corresponding field. The compressed folder should contain the ECG signal in SCP-ECG standard format. Figure 2 depicts a screenshot of the ECG upload process in OpenMRS platform. The same process can be accomplished using a mobile device as figure 3 depicts. Wearable or portable healthcare transducers with a Bluetooth interface that generate files in the standard format required by the system can also be used to this end for automating the upload process and minimizing the patients' intervention. The SANA mobile app for Android devices should be used, then, as the bridge for the communication of healthcare transducers with OpenMRS, enabling such integration. Apart from the patient, also medical staff, such as visiting nurses or doctors, can upload the biometric values of visited patient to the system using a computer or a mobile device as described earlier.

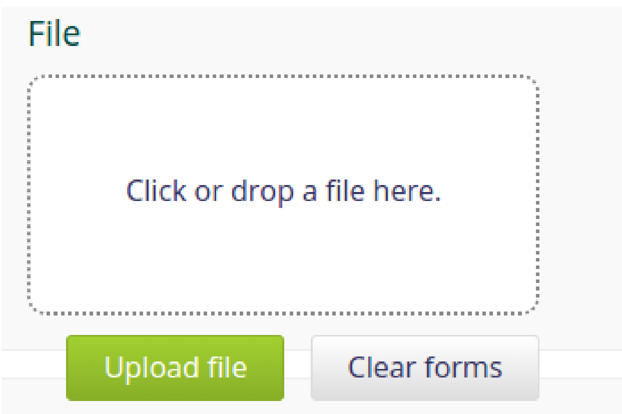

Figure 2. Dialog box for Biometric file's upload

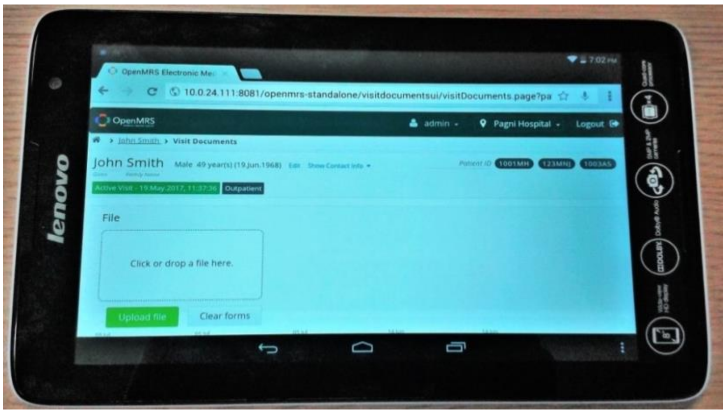

Figure 3. Biometric file's upload process via a mobile device

At the server side, the received values from the patient are stored in the patients record after appropriate processing. Here sophisticated signal processing or machine learning methods can be applied for facilitating doctor's work. But at the simplest implementation, the received values are just stored in the patients record for evaluation by the doctor. The doctor can access this information by any mobile or desktop device with internet connectivity. Once per day the patient and the doctor are virtually met using the Jitsi Meet video-conference facility offered by the system, so the doctor has a live view of the physical condition of the patient.

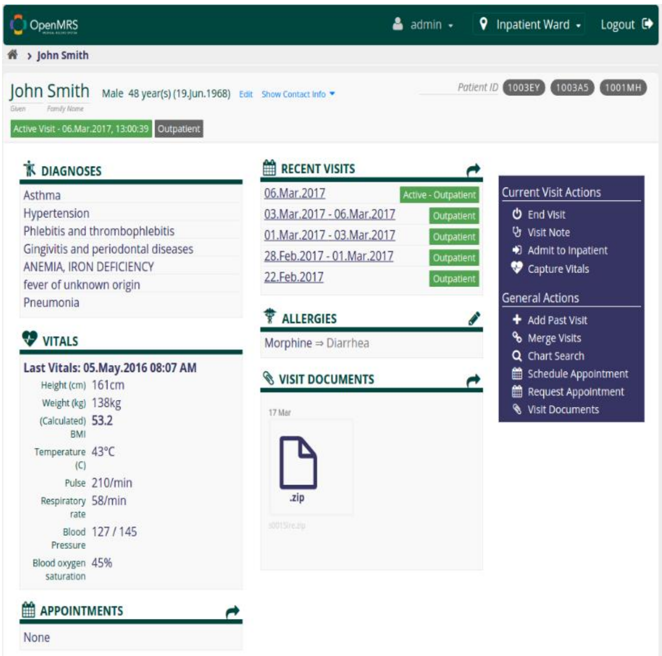

Figure 4. The patient's dashboard

OpenMRS provides a web application via which a doctor can have access and view every patient's dashboard as figure 4 depicts. Patient's dashboard includes personal information about the patient, such as his address and historical medical data (e.g., information about vitals or allergies or drugs) that are appropriate for the doctor to make a diagnosis. The doctor can view the Patient’s dashboard also via a mobile device as figure 5 shows.

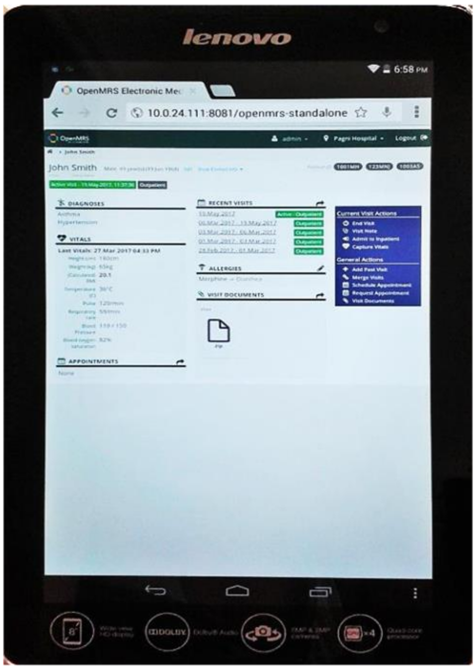

Figure 5.1 Patient's Dashboard in a mobile device

Before any biometric or medical values are inserted in a patient’s folder, a doctor should have initiated a virtual “Visit” for the patient. A “Visit” event takes place whenever the patient interacts with the system. This represents the conventional visit of patient to a doctor via physical presence in a hospital. A Visit starts when the patient checks-in at the clinic and ends when he checks-out. Similarly, the virtual visit will have a duration of one day, so it includes all the biometric values requested by the user for this day. In particular, the Visit comprises the encounters that are requested from the patient by the corresponding doctorand are categorized according to the date. The system also keeps a log of previous Visits in the patients’ dashboard.

The data storage process in our system follows the data hierarchy applied by the OpenMRS platform. The OpenMRS data model is divided into levels. The first level contains the Visit. Each visit is described by a unique visit_id. Data that are collected during a visit are called “encounters” and are part of the visit. A Visit can contain multiple encounters with different encounter_ids. Encounters consist of observations. Observation is regarded as a single unit of clinical information that is imported for a patient characterized by an obs_id. Each Observation includes Concepts that are any data we want to store for a patient.

Concepts have person_id as key value. Figure 6 depicts the Visit's data structure in OpenMRS.

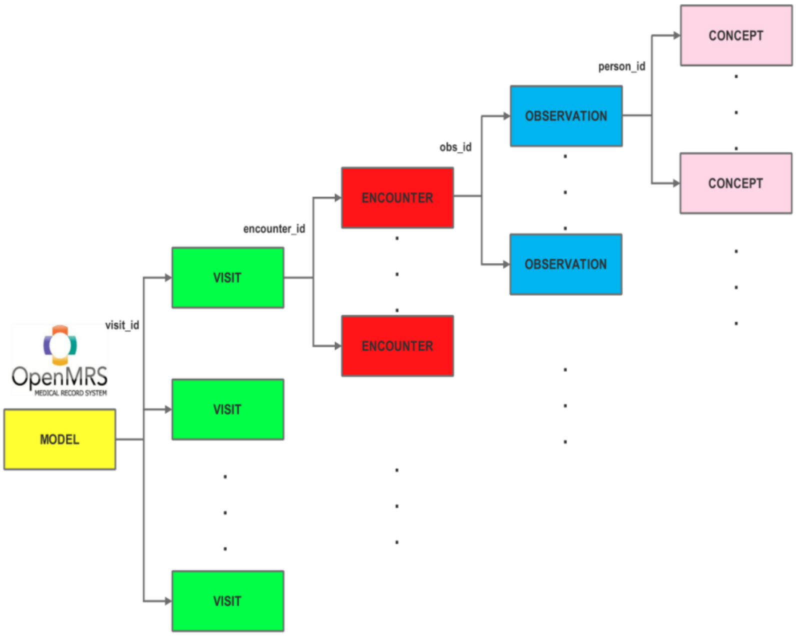

Figure 6. Medical Information Structure

For the current implementation, we shall create an encounter called Body Temperature, an encounter called SpO2 value, an encounter called Stethoscope and an encounter called Electrocardiogram (figure 7). A visit may include more than once the same encounter depending on the frequency that the encounter is repeated during a Visit. For example, the Electrocardiogram encounter contains several Observations, each of which comprises many Concepts for storing the associated with ECG medical values in the database. The encounters can be displayed or deleted if the doctor selects the corresponding fields.

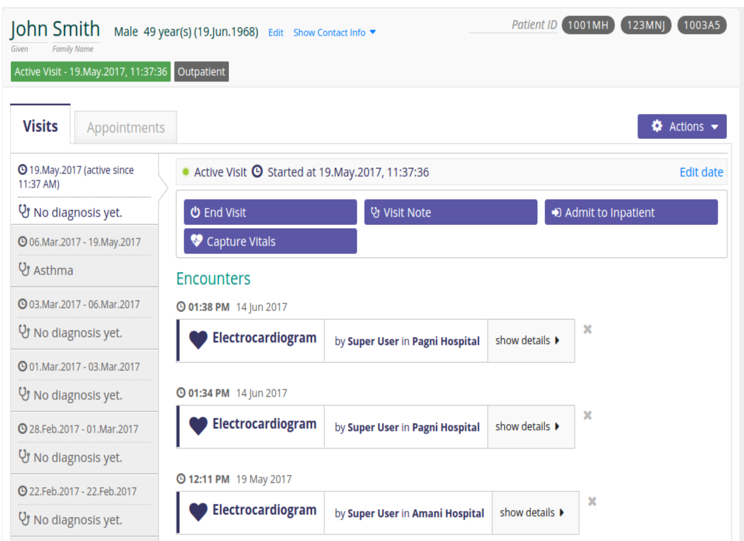

Figure 7. Patient's Encounters

Data are visualized using a form that OpenMRS provides. After the data collection, we use an HTML Form Entry module to display them. The HTML Form Entry module allows developers to create HTML forms and insert user data easily into the platform. We can use HTML for development but also JavaScript and CSS. Each value is stored into the database with a different identification number (id). Combining ids with jQuery allows us displaying these values.

Figure 8. ECG Visualization

Figure 8 shows an example ECG visualization as illustrated by the OpenMRS platform. Each plot describes the ECG signal in one of the 12-leads (I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5 and V6). ECG visualization is also feasible via a mobile device as figure 9 depicts.

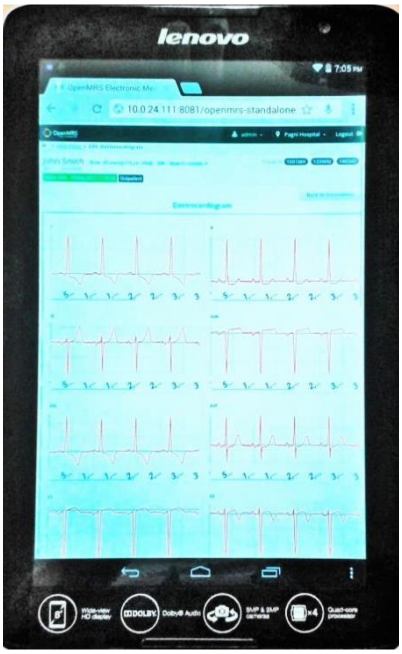

Figure 9.2 ECG Visualization in a mobile device

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