

EmERGE project: Evaluating mHealth technology in HIV to improve Empowerment and healthcare utilisation

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Abstract

The EmERGE project (<http://www.emergeproject.eu/>) will develop a mHealth platform to enable self-management of HIV in patients with stable disease. The platform will build upon and integrate the existing mHealth solutions operated by pioneering healthcare providers in the UK and Spain and apply a rigorous co-design approach to ensure patient and clinician input to the solution. The platform will provide users with web based (clinicians) and mobile device applications (patients) which interface securely with relevant medical data and facilitate remote access to key healthcare providers. EATG, the leading European HIV patient organisation, will provide a direct and deep interaction with representative patients and clinicians from 5 EU countries. The platform and interfaces will be validated in a large study of 3900 patients using a tailored Health Technology Assessment process: the Model for Assessment of Telemedicine applications, specifically developed for the assessment of mHealth solutions including translatability as a key factor.

1. Introduction

With the advent of effective antiretroviral therapy (ART) HIV is now regarded as a chronic illness with a normal life expectancy in individuals who have access to testing, treatment and care as in the European Union [1]. The vast majority of individuals have undetectable HIV viral loads (the aim of ART) on stable treatment and now seek to reduce the impact of HIV on their lives.

Individuals living with HIV are currently seen by an HIV clinician every 3-6 months according to national and international guidelines [1]. Given that the number of new

diagnoses and onward transmissions are at best stable, if not increasing [2], in association with longevity, the number of patients requiring treatment and care continues to increase year on year. In the current era of austerity there is little or no additional resource to manage this increasing workload without a substantial increase in capacity which is unlikely to be forthcoming. Therefore it is imperative that new models of service provision are explored and evaluated.

mHealth solutions offer an opportunity to provide alternatives to traditional care that can reduce appointments for stable patients and increase capacity to those living with more complex disease. A key recommendation from a recent review of literature on mHealth for HIV treatment and prevention [3] was the need to provide actionable evidence on how to improve HIV care through incorporation of mHealth solutions integrating technologies into existing programs rather than using (to date) externally driven, isolated projects.

In this regard, the EmERGE project will develop a mHealth platform which will be integrated with clinic ICT systems and which will be used to reduce face-to-face appointments in patients living with stable HIV and to complement appointments in those with more complex medical needs.

2. EmERGE platform requirements

The EmERGE project have performed a situational analysis and background assessment to inform the

development of a mHealth platform in HIV. The main objectives were:

- assess clinical settings and models of HIV care in clinical sites
- assess the ICT infrastructure and data security requirements in clinical sites and countries, and
- assess data already captured to assist the health economic analysis

This process has allowed us to get a detailed idea how people living with HIV currently are followed up in the five clinics that participate in the study. Various aspects were recognised: which activities at present guarantee the medical and psycho-social follow-up, which cadres are involved, which laboratory tests are done, which other investigations are possible, who pays for all of this, what kind of patient file is used, how are data stored, how does communication with other health workers happen etc.

Detailed questionnaires were designed to capture all this information, covering ICT infrastructure and security requirements, HIV-care organization, information governance and the ethical-legal frameworks.

A co-design process has been also performed where people living with HIV (PLWH) and clinicians have expressed their views concerning the design and components of the proposed mHealth platform. There has been a total of:

- 7 workshops with PLWH,
- 20 individual interviews with PLWH,
- 3 mixed workshop with PLWH and clinicians, and
- 3 workshops with clinicians

Through these methods the project have included 97 PLWH and 51 clinicians. Participants deliberated on the core functionalities of the proposed platform and highlighted opportunities and concerns as well as other functionalities that could be useful for managing HIV.

3. EmERGE platform specification

Overall, the goal of the EmERGE platform is to provide relevant, timely and secure delivery of health care data to suitable Patient Users with stable HIV disease through the use of novel mHealth tools. In the case of this project this involves the construction of a 'stack' of software that integrates into pre-existing IT systems in place at each of the clinical sites.

An overview of the proposed stack is shown in Figure 1. The stack fundamentally consists of two applications; the Web Application and the Mobile Application. The Web Application is hosted on a server at each clinical site and provides two services. The Clinical User Application represents the software and associated interfaces that Clinical Users interact with. The API Adapter is a site-specific service provided by the Web Application that provides the necessary interface with local clinical and demographic systems, via their respective APIs.

The Mobile Application is also made up of two components: The Patient User Application and the

Messaging Service. The Patient User Application represents the iPhone or Android application that is used by Patient Users on their mobile devices. The Messaging Service represents the Cloud Service used to relay messages securely from the Clinical User Application to the Patient User Application.

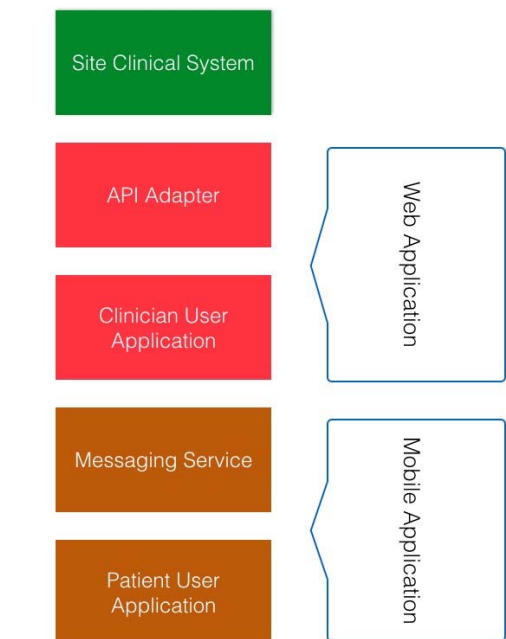


Figure 1. EmERGE platform stack

Regarding the technology involved, the Web Application is being constructed using Ruby on Rails and the Mobile Application with the Ionic Framework. Each clinical site requires an 'API Adapter' as part of the web application. This will be constructed on a site-by-site basis. The recommended messaging languages are JSON and XML. The main communication interface will be through HTTP/1.1 (June, 2014). Use of HTTP over TLS (HTTPS) will be used where possible. The external Messaging Service will be provided by a Cloud Server. Amazon Secure Data Centers utilizing Amazon Service technology with accreditation under ISO 27001. A third party, Firebase (<https://www.firebase.com/>), is considered for use in hosting the infrastructure for passing of messages to the Cloud Server.

3.1. Web Application

The main functionalities of the Web Application are:

- **Login:** Clinical Users will require a unique username and password to be able to login to the Web Application.
- **Dashboard:** on successfully logging into the Web Application, Clinical Users should see a dashboard with clear options about potential uses of the system. There will be links to:
 - Add a new Patient User
 - View 'virtual clinic' appointments and calendars
 - View and filter a list of all registered Patient Users

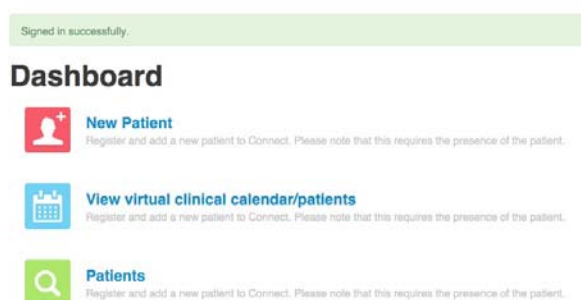


Figure 2. Dashboard of the Web Application

- **Patient User Device Registration:** Registering a Patient User and their associated mobile device is required for them to receive data from the Web Application (through the Messaging Service). The process of registering a Patient User will require the presence of the patient in an appointment setting. Prior to device registration necessary consent should be gained, and relevant documentation signed by both Patient User and Clinical User.
- **All Patients:** In this area of the Web Application Clinical Users will have full access to Patient Users who are registered on EmERGE platform (at their clinical site)
- **Patient User View:** This vital area of the web application is where Clinical User(s) have an overview of each Patient User. It is used during 'Virtual Appointments' in order to review data that will be sent to the Mobile Application. It will include:
 - Current Medication List (including name of medication, dose/frequency and date of commencement)
 - Blood Test Results (including viral load, CD4 count, liver and renal function and electrolytes). This data should be shown both graphically and in a table format for easy review.
 - Appointment Lists
- **Virtual Clinic Calendar:** a Virtual Clinic Calendar will be provided to Clinical Users. This provides an overview of when reviews of specific patients are required.

A number of actions may be taken by the Clinical User. These include:

1. Authorisation – this will send the data for the most recent blood tests results and medication lists to the mobile application for the specific Patient User.
2. Re-booking – this will re-book the patient for a future review of medication and blood tests (appointments may be viewed in the calendar).
3. Pausing – this will pause the patient in the system. It is anticipated that this function will be used if the patient requires closer follow-up in person, but they wish to remain on the system.

3.2. Mobile Application

The requirements for the mobile application are:

- **Authentication:** Patient Users will be required to login to the application on each use. This is necessary to conceal the nature of the application in case of phone loss/theft.
- **Dashboard:** the dashboard should provide a single point of entry for a Patient User, allowing them to easily see all options that are available within the Mobile Application. This will include links to:
 - Medication List
 - Blood Test Results (current and historical)
 - Appointments
 - Activities
 - Healthcare Information
 - Account Information

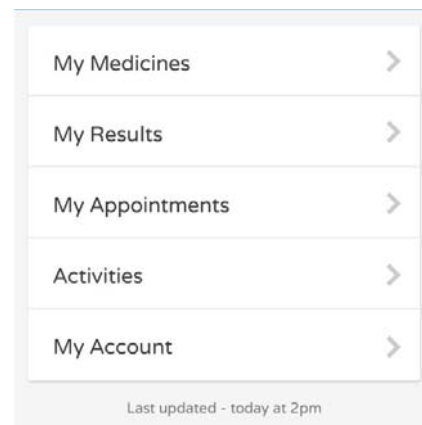


Figure 3 – Dashboard of the Mobile Application

- **Medication List:** this view will show a list of current medications, including dose and frequency. Information about each medicine should be easy to understand for the Patient User, avoiding the user of technical terminology.
- **Results:** blood test result information, both current and historical, will be displayed in this view. This data should be stored locally on the device, having been previously retrieved from the Messaging Service. Only blood test information authorised from the Web Application (following a 'Virtual Appointment') will be visible.
- **Appointments:** in this view the Patient User should be able to see information about upcoming appointments. This data should be retrieved from the Messaging Service. Users should be able to add appointment information to their mobile device calendars, and set reminders/alerts.
- **Activities:** the Activities view acts as a comprehensive log of all data transmissions that have been received by the Mobile Application from the Messaging Service. These should be easy to understand for the Patient User, and include the following localized timestamps:
 - Appointment Updates
 - Blood Test Result Updates
 - Medication Updates
 - Access/Registration Updates
- **Account:** this view provides the Patient User with a comprehensive overview of the current status of their account within the EmERGE platform. It should

display whether their account is active or inactive, as well as the date of activation. Patient Users will have options to:

- Turn off mobile-wide notifications
- 'Unlink' their account from the Messaging System (resulting in the account becoming inactive in the web application)
- Erase application data

4. Clinical study design

A large prospective cohort study, undertaken in five European sites will be performed to validate the EmERGE platform which enables self-management of HIV in patients with stable disease using a tailored Health Technology Assessment (HTA) process, Model for Assessment of Telemedicine Applications (MAST) [4]. The MAST approach was developed as part of an EC initiative aiming to provide a structured framework for assessing the effectiveness and contribution to quality of care provided by telemedicine applications and is based on the EUnetHTA core HTA model. MAST provides a framework for an evaluation especially developed for telemedicine, and suited to mHealth. This evaluation will look at a number of aspects including: empowerment, health economics, sociotechnical aspects, clinical outcomes, patient related outcomes and quality of life.

The site recruitment will be sequential and the recruitment period will last 18 months at each site, so a maximum follow-up of 35 months will be undertaken. Study visits will take place at baseline defined as the time of mHealth introduction, months 6, 12, 18, 24 and 30. The five clinical sites involved in the study are:

1. Fundacio Privada Clinic per a la Recerca Biomedica, Barcelona, Spain
2. Brighton and Sussex University Hospitals NHS Trust, Brighton, United Kingdom
3. Institute of Tropical Medicine, Antwerp, Belgium
4. Klinika za infektivne bolesti "Dr. Fran Mihaljević", Zagreb, Croatia
5. Centro Hospitalar de Lisboa Central, EPE, Portugal

5. Conclusions

It is estimated that 86% of EU deaths are now due to a chronic disease [5]. The burden of morbidity and disability is also increasing and disproportionately affecting disadvantaged communities across the EU [6]. It has recently been reported that there are over 97,000 health related apps on the market with 70% targeting fitness and well-being. Apps are used for helplines, improving compliance, appointment reminders, community mobilization, health promotion, raising awareness, telemedicine, surveillance, patient monitoring, information initiatives, decision support system and patient records [7]. Whilst there is interest and enthusiasm for the use of apps, they have yet to enter mainstream healthcare provision [8].

In particular, there is a high uptake rate and use of mHealth in HIV patient populations. In this context, EmERGE will develop a widely usable mHealth platform for the treatment and care of HIV in five European

clinical sites and evaluate the value of the platform using the EU recommended MAST methodology before taking the platform to market. EmERGE aims to demonstrate the benefits to patients and simultaneous increases in cost-effectiveness for healthcare providers by reducing face-to-face consultations.

In the early stage of the project, the EmERGE study is investigating whether mHealth provides an improvement of empowerment and a cost-effective alternative to frequent routine HIV outpatient clinic appointments for patients with well controlled stable HIV infection. Enhanced functions will be explored as part of the co-design process and offer the potential in patients to add to existing healthcare provision by improving interaction and information between different healthcare providers and so personalising HIV outpatient appointments with improved utilisation of multi-disciplinary teams.

Acknowledges



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