Future of mHealth in Europe
Lessons learned from the EmERGE project

Virtual Stakeholders Meeting Report

2 September, 10.00 – 16.30 CET

Highlights

EmERGE was a 5-year project funded by the European Commission H2020 Programme that developed an mHealth platform to enable self-management of HIV in patients with stable disease. The digital health pathway and platform were developed with a rigorous co-design approach to ensure patient and clinician input to the solution. EmERGE provides users with a mobile device application which interfaces securely with relevant medical data and facilitates remote access to key healthcare providers. The EmERGE platform has been validated in a large study of over 2,200 patients in Belgium, Croatia, Portugal, Spain and the UK, using a tailored Health Technology Assessment process, specifically developed for the assessment of mHealth solutions.

Patient empowerment is seen as a critical development in the management of people's health and has been the focus of improving healthcare. The WHO has developed its integrated person-centred services as an important strategic direction to more actively involve patients as partners in healthcare governance, development and implementation. Furthermore, the EU has designated the importance of empowering European citizens to manage their own health care through digital transformation of health within the Digital Single Market. The goals are to ensure that patients have access to their data; that their data remain confidential; and, that information systems' integrity are protected.

In the context of discussion on digital transformation in health care that is person-centred, the EmERGE project brought together different stakeholders to examine the findings of the intervention. Participants discussed lessons learned and implications for scale up and transferability to other sites and its applicability as a care pathway in other areas. The meeting convened communities of people living with HIV, health care professionals, researchers and policymakers at national and EU levels. Given that the role of digital health has become even more important in 2020, the meeting also explored lessons from the recent COVID-19 health crisis, the role and use of telemedicine and digital care pathways.[1]

The meeting attracted 69 registrants with an average of 53 participants per session, most of whom attended all three of the main sessions. Most of the participants were EU based. In the context of COVID-19 and the overabundance of online events, targeted outreach to key stakeholders to stand out from all of the email and social media information noise was an important factor in attracting participants. The working groups were also well attended but most participants observed while a handful of persons actively interacted with the facilitators and each other.

Part I of the meeting provided results and experiences generated by the EmERGE project. Quantitative results showed that those using the EmERGE pathway maintained excellent HIV viral load outcomes and quality of life measures (as with traditional pathways). EmERGE showed that this mHealth solution helped clinics to manage capacity; and provided non-ART related cost reductions for patients and clinics; it has been acknowledged as clinically valid options for patients and clinicians. The co-design methodology used in the EmERGE project resulted in trusting, long-lasting relationships that promoted effective design and implementation. In-country experience from both clinicians and patients demonstrated overwhelmingly positive feedback. Some concerns still exist with respect to perceptions around data security and, encouragingly, the desire to further enhance the EmERGE app to include health literacy and other diseases.

Part II provided insights from different stakeholders at the EU, country, facility/clinician and person living with HIV levels. They discussed the policy, clinical, social, economic and technical opportunities and challenges that mHealth solutions such as EmERGE offer. The majority of stakeholders see mHealth as an opportunity for providing a choice to people living with HIV to improve empowerment in the management of their own health. Challenges remain, including lack of technical standards, interoperability and the reliance on technical solutions in the absence of real changes to the clinical practice technology is meant to support.

Part III dealt with the impact that COVID-19 has had on health systems and the role that mHealth has played. Suddenly, clinical services were faced with supporting patients at a distance with little or no notice. There were concerns around the lack of consultation with patients. This contrasted with the experience people living with HIV had with EmERGE's co-design methodology. However, insights into how EmERGE could be expanded to proactively reach out to vulnerable populations and become expanded to new diseases provide optimism for the role of mHealth in support people during challenging times.

Pieter Vanholder, the Executive Director of EATG welcomed everyone to the day's meeting, indicating that, while it was a shame that the meeting could not be held in person, there was something fitting about using technology to talk about EmERGE as a technical solution. He explained that EmERGE was developed to improve the quality of life of people living with HIV and to support self-management of their HIV disease. The participation of EATG was important and resulted in a rare example of community involvement in the form of a true partnership. Pieter thanked all of the many partners involved and those taking part in the day's sessions, highlighting the objective to share among stakeholders the lessons learned from EmERGE and what this means for future mHealth solution implementation.
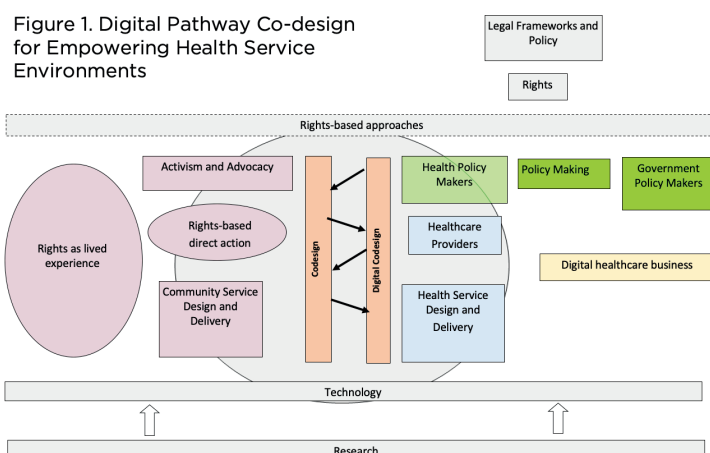
Jenny Whetham from Brighton and Sussex University Hospitals NHS Trust, UK presented the quantitative results from the EmERGE project, which was a 5-year project involving 12 partners, including the study sites. The first year looked at the assessment of needs and the initiation of co-design. From a technical perspective, there were many challenges in developing systems and integrating them into clinical sites. The study was designed following the Model for Assessment of Technical Applications (MAST) framework. Data were collected 12 months prior to and 12 months after implementation of the EmERGE application.

The project demonstrated that there is a role for digital health pathways in person-centred care for people living with HIV and that this is a feasible and acceptable option in the menu of care. EmERGE was found to be a secure, trusted, co-designed pathway and platform that provides access to people's own data. Virological outcomes remain excellent and patient activation high in this population. Health-related quality of life measures scored highly with stigma remaining a key area of concern for some locations. EmERGE helped clinics to manage outpatient capacity by freeing up time for more complex patients. Usability and patient experience were good, underscoring the importance of co-design. Data security was excellent with no data breaches during 3891 patient years of follow up. Due in part to the EmERGE project, the EACS guidelines were changed to support non-face-to-face consultations (email, phone or other electronic means) with the recognition that they have the same clinical validity as face-to-face consultations.

Mary Darking from the University of Brighton, UK presented the more qualitative results from the EmERGE project. The main design feature of the EmERGE application was co-design with active and continuous involvement of all stakeholders, with a focus on inclusive innovation for the end users, with the end users in a manner that creates and promotes inclusion. Co-design sets the stage for the creation of better design, with the user experiences driving technical decisions. Co-design provides opportunities for ongoing accountability to end users and stakeholders due to iterative inclusive interactions with them. Co-design can also extend to business and continuity planning with the development of lasting relationships after having built in co-design costs from the beginning.

EmERGE co-design involved workshops and interviews over 5 years in 3 phases. The workshops and interviews were facilitated by community partners and annual community partner network meetings took place.

- Phase 1: 97 people living with HIV and 63 clinicians
- Phase 2: 72 people living with HIV and 32 clinicians
- Phase 3: 5 workshops at each clinic including both people living with HIV and clinicians

Figure 1. Digital Pathway Co-design for Empowering Health Service Environments

Josip Begovac from the University of Zagreb, Croatia provided the clinician's perspective on the implementation of EmERGE at the country level. In Croatia, there is only one HIV centre for the entire country. Patients must travel to the centre to receive care, receive their ARTs, attend the laboratory and get results. EmERGE allows for results to be safely sent to patients, eliminating the need for them to return to the clinic. Depending on where patients live, this can dramatically reduce travel time and costs. EmERGE frees up clinic time for more complex patients and improves communications with people living with HIV. There is potential for EmERGE to be used for other clinical applications, including PrEP, STIs, hepatitis, diabetes and hypertension. The utility of the EmERGE app is particularly valuable for diseases that generate stigma and discrimination for patients.

Sanja Belak Skugor & Tomislav Vurusic from the NGO Lux Vitae in Croatia presented country-level experiences from the perspective of people living with HIV. Co-design resulted in a good collaboration between different actors who were involved together from the beginning. This built upon the principle of "nothing for us without us", providing a sense of ownership and real involvement in the process. Some of the challenges included ongoing stigma, the issue of disclosure, sometimes difficult relationships with clinicians and fears around confidentiality.

The implementation of the EmERGE app yielded benefits, such as ownership of one's own health data; time and money savings associated with travel; less uncertainty about one's health status; increased motivation around health behaviour; and the ability to preserve anonymity and avoid stigma. Some of the drawbacks include the perception that the data are not secure; the lack of 2-way communication with clinicians; insufficient health literacy; becoming obsessed with checking health data; and the lack of social support on the app. Co-design enhanced empowerment for patients who discovered they could voice their needs on clinical and technical issues. In the future, it will be important to also focus on improving health literacy.

Part II: EmERGE, mHealth and Health Systems in the EU;

Session moderator: Kevin Moody

Part II began with a short presentation from Kevin Moody summarising the top-level information found in the Policy Brief: *How EmERGE has addressed barriers in implementing mHealth in the EU*. He highlighted the need for integrated, person-centred services as outlined in global frameworks and standards that have been developed by the World Health Organization, the Global Network of People Living with HIV and through advancements in thinking on issues related to quality of life in the continuum of care. This was followed by a description of the expected advantages of digital solutions in health that include empowering patients, connecting patients and clinician, decreasing inequality and providing options for vulnerable populations. Kevin then discussed the various questions that the policy brief attempted answer around the opportunities and challenges for implementing mHealth solutions at the health system and clinic level; user (patient and clinician) level; and in terms of innovation and implementation.

This was followed up by a panel discussion with the following invited guests:

Patient groups: Ricardo Fernandes, Executive Director, GAT Portugal
Clinicians and health facilities: Christoph D. Spinner, Klinikum rechts der Isar, Technische Universität München, Germany
National health systems: Hrvoje Belani, Country e-Health and Cybersecurity, Ministry of Health, Croatia
European Union: Ander Elustondo Jauregui, AI, Data and Digital Health Services, European Commission

The panel guests were asked 3 questions on the (1) opportunities and (2) challenges of implementing and scaling up mHealth solutions and (3) what needs to be done to prepare for implementation and scale up.

Perspective	Opportunities	Challenges	Preparation Needed
People living with HIV	Stigma addressed – fewer trips to facility and interactions with those who might stigmatise. Reduces burden of follow up. Reaches vulnerable populations. Provides data source to share with partners to prove undetectability.	Many people in some countries do not have access to smartphones or data plans. People are afraid of lack of data security. The app does not solve other logistical issues, such as needing to go to facilities for bloodwork or for picking up prescriptions. It is important to address value, not cost because many people think digital health solutions are too expensive.	Value must include more than costs. Also look at advantages, such as reduced travel. mHealth solutions need to be accessible (including cost) for the most vulnerable people and be sure to leave no one behind. mHealth solutions need to be flexible and adaptable to different contexts in different countries and settings.
Clinicians and health facilities	Improves doctors' experiences in communications with patients. Allows for research into novel approaches to care. For example, biomaterial via the post, telemedicine and continuous clinical monitoring. Provides data in the hands or patients.	Data protection and confidentiality. Important to articulate opportunities for both the clinician and the patient. It is hard to get structured data that speaks to all systems.	Need to look at economic aspects: clinicians currently face additional costs but are not reimbursed for e-services. Patients are strong drivers – there is a need to generate demand. Assess value of apps, not only in terms of cost to develop but also cost and value to patient.
National health systems	Better access to services, especially in countries where long distances play a role. Potential for continuous clinical monitoring (glucose, heart rhythm, etc.) Innovative support for other health applications (e.g. COVID-19)	Implementation is challenging. Data security is a problem. Technology doesn't replace face-to-face care pathways. Systems need to change in order for mHealth solutions to be able to work.	Country-level certification for mHealth solutions including clinical and non-clinical aspects. Ensure that applications from different providers can interact with country-level systems. Enforcing standards for eHealth and mHealth to provide for interoperability.
European Union/ European Commission	Strengthen mHealth applications to support continuous tracing and monitoring. Explore centralised versus decentralised data storage solutions with an eye to provide patients with information and security. Explore cross-border data sharing to serve citizens but also to develop better health policies based on secondary use of data.	Identify where there are gaps in data protection. Lack of national legislation. Different rules by country for certification and reimbursement. Interpretable data exchange so that systems talk to each other. Need to integrate tools into clinical workflow.	Important to expand on the use of current systems, such as the European Health Data Space that promotes patient empowerment; the Resilience and Recovery Facility; and the EU4Health programme. Work on EU standardisation of data to facilitate cross-border exchange of Patient Summaries and ePrescriptions.

Conclusion: The stakeholders at this meeting have echoed many of the summary recommendations in the Policy Brief, which can be here. (https://www.emergeproject.eu/policy)

![EmERGE logo]

Part III: Lessons from the COVID-19 Crisis and the role of digital pathways in HIV prevention and care;
Session moderator: Ludwig Apers

Ludwig Apers from the Institute of Tropical Medicine Antwerp provided an introduction to the influence of COVID-19 on clinical practice from the perspective of his own clinic. Between 2019 and 2020, one can see that clinic consultations decreased significantly, especially when comparing April and May of both years. At the same time, telephone consultations increased. This was in part due to the fact that, before COVID-19, telephone consultations could not be charged by the facility to the health system. This changed in March 2020. The clinic was closed down, except for those with active clinical symptoms related to HIV or STIs. Those with COVID-19-related symptoms were not allowed into the clinic. The clinic saw an enormous decrease in STI diagnoses in this period.

Colleagues at the Institute of Tropical Medicine conducted a survey to ascertain measures of physical contact and mental health. They found that close physical contact with non-steady partners decreased markedly after the 18th of March. This held true for all categories of contacts, including gay friends, hetero friends, colleagues and family. Only contact with steady partners decreased at a lower rate. The investigators looked into mental health aspects and found that loneliness among respondents increased after physical distancing measures were implemented. This included feelings of lacking company, feeling left out and feeling isolated. For people enrolled in the EmERGE programme, it was fast and easy to send messages to advise people how to deal with their HIV care services during lockdown, including how to deal ART refills. A few people who were not enrolled in EmERGE missed their ART refill dates and ended up with extremely high viral loads. They would have benefitted from being part of the EmERGE programme.

Daria Alexeeva from AIDS Foundation East West in Amsterdam and Koen Block, who played a role in the EmERGE project and was EATG's Executive Director until 2018, facilitated breakout sessions that aimed to answer a number of questions related to the use of mHealth applications in countries; their advantages for use during periods of lockdown; the potential for EmERGE to reach groups other than "stable" patients; and whether or not mHealth can assist in preventing loneliness and isolation. The following is a summary of the discussions that took place during the breakouts.

Question	Answer	Next steps
What is the current situation for mHealth in your country	Currently, only urgent blood tests are done in Scotland. There has been no consultation with people living with HIV associations. This could have happened digitally, but it didn't. The UK CAB continued, so this would have been possible. There is currently no regulation. This might have consequences for later. Only those with low CD4 were invited for service. Zagreb: the hospital turned into a COVID-19 clinic. Services were decreased in the STI clinic, there was less HIV testing and less PrEP. The community testing site was closed. There were no clients because they could not travel. There were no routine visits. The main activity was sending ARVs to patients.	HIV associations should be consulted when there are changes within the system. There should be more synchronisation in different practices to avoid surprises. There needs to be more interactions between the medical sector and patient groups because other factors must be considered. Establish closer links with other organisations working on guidelines. (e.g. EACS) In the future, embed telemedicine in services. Telemedicine can replace face-to-face consultations. mHealth can be better coordinated. It is important to maintain systematic contact with patients.
What advantages do you see for mHealth especially at times such as lockdown?	Home HIV and STI testing is already available and can be a very good space for telemedicine. It is important to not leave people behind. We need to manage equal access. Digital health literacy needs to be taken into consideration. It's difficult to recruit people using drugs and women living with HIV. Online peer support; increased demand from the community. The app gives some emotional/psychological support for empowerment. When people know you (healthcare) are there, the biomedical device has more opportunities. The app is currently oriented to clinical services. This should be expanded.	People were forced to go online and get familiar with the platform, which is an asset. Building trust for the online medium and managing control of the engagement. Concerns about security and sharing online data. There are still design challenges. Messages are easy to send to a large group, increasing connectedness. People should be able to choose whether they want to use the online service or traditional service, including mental health services. The app is one of many possible solutions but not the only solution. The app could possibly build bridges to other services (psycho-social, co-morbidities). Can be important to break isolation, even if it's only in one direction.
EmERGE was designed for "stable" HIV patients. Are there others who could be reached?	Minorities and ethnic communities. Widen the criteria on who can be included in EmERGE Allow people to self-select More proactive approach for vulnerable groups. Patients could use the app in different ways instead of the current "all or nothing" approach. People who live far away would benefit from the app.	Don't wait for them to come to you. Be proactive. Organise a campaign to advertise the app. Make use of the momentum created by COVID-19.
Could EmERGE give an answer to isolation/ loneliness?	The people we miss because of COVID-19 are exactly the ones who were not eligible for EmERGE during the study People who are afraid of getting COVID-19 will avoid the clinic. Online platforms can help to bring people together.	

Project Leaders and Partners

- Brighton And Sussex University Hospitals NHS Trust - United Kingdom

- European Aids Treatment Group (EATG) - Germany

- University Of Brighton - United Kingdom

- Institute of Tropical Medicine Antwerp - Belgium

- Fundacio Privada Clinic Per A La Recerca Biomedica - Spain

- University Of Sussex - United Kingdom

- Centro Hospitalar De Lisboa Central, Epe - Portugal

- Klinika Za Infektivne Bolesti "Dr. Fran Mihaljević" - Croatia

- NPMS-HHC- CIC - United Kingdom

- Universidad Politecnica De Madrid - Spain

- EmERGE mHealth Ltd – United Kingdom

- MODUS Research and Innovation