Deliverable 8.5: Policy Brief
How EmERGE has addressed barriers in implementing mHealth in the EU

Dissemination Level: Confidential (CO)

Owner

Name: Ann Isabelle von Lingen	
Lead Beneficiary: EATG	
Phone: + 32 491348317	
Email: annisabelle.vonlingen@eatg.org	

Author(s): Kevin Moody (Ann Isabelle von Lingen)

Work Package: WP8

Task: D8.5

Document Status

Version: 1.0

Last modified: 20200227

Status: Final

Approved by: J Whetham

Date Approved: 28/02/2020

Table of contents

Table of Contents

Summary

This policy brief describes barriers that exist when implementing mHealth solutions and how the EmERGE project was able to anticipate many of these and, where unexpected challenges arose, how the project was able to manage them.

In this policy brief, information from literature and grey literature sources illustrate the types of challenges that mHealth product implementation faces. This is compared and contrasted with examples from the EmERGE project itself, in order to paint a picture of how EmERGE was able to overcome these challenges. This brief draws on both the findings from the literature and the experience of the EmERGE project. It highlights key learnings to be considered in the potential scale up, adaptation of this mHealth and similar digital solutions. This paper does not present a comprehensive summary of the outcomes of the project or the experiences of the users.

It is important to note that EmERGE was not set up as a mechanism to reduce healthcare costs. Rather, the mHealth product was developed to offer patients and clinicians an additional clinical pathway option for stable HIV patients, giving them better access to their clinical data and alternate mechanisms for communicating with their healthcare providers in between appointments. Many of those who chose this pathway experienced reduced time spent at clinics and travelling back and forth. Healthcare providers experienced an increase of available clinic time in which to engage with people with more complex HIV-related issues.

Challenges and Recommendations

A: Trust in the platform

From conception, the EmERGE project addressed concerns about privacy, quality of care and patient safety. The fact that this was an EU-funded, clinically led project allowed for the development of trust among stakeholders. Had this been solely a commercial enterprise, led by non-clinical players, it would have been difficult to engage meaningfully with stakeholders and build the trust needed to develop such a product for HIV disease management.

1. Product developers and clinical implementers should ensure that their projects are led by clinically oriented goals and objectives, with full participation by stakeholders.

B: Costs

Cost of commercial mHealth services, access to sources of funding and lack of financial reimbursement for virtual appointments represent barriers to adoption.

2. Where possible, secure funding ahead of time to help free up stakeholders' time and to be able to anticipate and address technical challenges. Where *a priori* funding is not feasible, leverage the partners to work together to find funds for this stage.
3. Include non-monetary value and opportunity costs into assessments of cost-effectiveness. HIV treatment will remain the costliest aspect of HIV care. mHealth interventions will provide added value for all stakeholders (clinics, clinicians, patients) in important areas other than direct reduction of service costs.
4. Funders should anticipate the need for sufficient funding for all parties in order to compensate for time spent by stakeholders on adapting and implementing the mHealth intervention as part of the co-design approach.

C: Technology

Technology capability and infrastructure of local clinical settings vary considerably across EU countries. Change in technology occurs rapidly and is variable from country to country and clinic to clinic. Background assessment and capability building support may be required for mHealth solutions to be feasible.

5. Implement mHealth interventions in a decentralised manner, taking into consideration local capacity.
6. Anticipate technological change, especially with respect to alternative and competing systems. As part of assessments with stakeholders, determine the added value of a separate HIV app and how it fits within or beside other national or clinic-based systems.
7. Product developers should weigh the importance of investing in time to develop relationships among stakeholders against remaining impactful in the fast-changing environment of technology innovation.

D: Stakeholder engagement: Clinics, healthcare providers, patients

Recognising when mHealth incorporates both clinical and patient users enables support for clinical pathway redesign and workflow challenges to be addressed. Mechanisms for ensuring that partnership and collaboration are embedded in ongoing product development – such as a product user group structure – should be mandatory.

8. On initiation of the project, invest in partnerships with clinics, healthcare providers, users and other stakeholders in order to achieve consensus and buy-in.
9. Implementers should invest in stakeholder relationship building from the start and embrace a co-design approach to developing and implementing mHealth innovations.
10. People living with HIV networks and organisations should advocate for mandatory involvement in mHealth initiative development and implementation.
11. Utilise a co-design approach in order to bring together stakeholders, reduce power inequalities and empower patients.
12. Implement mHealth interventions in a decentralised manner, taking into consideration the needs and restrictions of local users. This includes important issues related to HIV-related stigma and discrimination.

E: Clinical outcomes and quality of life benefits

mHealth interventions will not automatically provide clinical or quality of life benefits to patients unless they are paired with efforts to empower people to become more actively involved in the management of their HIV disease.

13. Implement measures to improve health literacy among users of mHealth technologies, by embedding functionalities in the app and/or engaging with patient groups (people living with HIV networks).
14. Further investigate the utility of mHealth in supporting people to be empowered to engage more meaningfully in their own health care, including being better connected to their healthcare workers between appointments.

1.0 Introduction

This deliverable is a policy brief describing how EmERGE has addressed challenges in implementing mHealth in the EU. More specifically, this brief outlines opportunities and challenges faced by the EmERGE project and how these were either overcome or left unresolved. The purpose of this brief is to inform stakeholders who intend to implement EmERGE or to develop and roll-out similar mHealth solutions on what to expect and how to manage issues along the way.

In this policy brief, each section describes anticipated issues in implementation that have been sourced from the literature (including grey literature, such as websites). Evidence from the EmERGE project is then highlighted to demonstrate how processes that were implemented were successful in overcoming these barriers or to illustrate how these concerns need to be addressed in future implementation projects.

EmERGE[1] is a project funded by the European Commission H2020 Programme (grant number 643736). EmERGE has developed a mHealth platform to enable self-management of HIV in patients with stable disease. The platform builds upon and integrates components of effective mHealth solutions developed with a rigorous co-design approach to ensure patient and clinician input to the solution. It provides users with a mobile device application which interfaces securely with relevant medical data and facilitates remote access to key healthcare providers.

HIV has transformed from a deadly infection to a chronic condition. As people take treatment longer and age, they are susceptible to multiple morbidities, many of which are also chronic. Evidence suggests that self-management of HIV disease is important to improve clinical outcomes; however, traditional services are expensive and time-consuming. Digital health solutions provide a strategy to support self-management (Cooper et al. 2017). The EmERGE project was designed to enhance the empowerment and engagement of people living with HIV in their own HIV disease management (EmERGE Deliverable 2.4 2020).

The need for more integrated, person-centred services has been recognised globally by the World Health Organization (WHO) as an important strategic direction for global health. Within its framework (WHO 2016), the WHO has identified the essential role of patients as co-creators of healthcare, through programme governance, development and accountability.[2] As increasingly more patients become stable in their HIV disease, attention is moving towards more holistic descriptions of the quality of life, encompassing a comprehensive and integrated approach with more decision-making at the person, family and community level (Frontline AIDS 2018). This is further strengthened by initiatives to move health care services beyond traditional service delivery systems, including the increased attention to self-care, including HIV and STI testing and contraception, which puts the patient in direct control of decisions related to diagnosis and treatment (WHO 2019).

mHealth interventions provide information and communications functionalities in the hands of patients through their mobile devices. Most eHealth interventions for self-management are simple in nature, targeting only one or two functions, for example, adherence, appointment reminders, smoking cessation, etc. Few are complex enough to facilitate a range of self-management behaviours (Cooper et al. 2017).

[1] https://www.emergeproject.eu/
[2] https://www.who.int/servicedeliverysafety/areas/people-centred-care/Overview_IPCHS_final.pdf?ua=1

Digital systems for health are seen as important in the coming years for EU countries to be able to support patients and their health providers, empower people with control over their personal data, facilitate research, and support the development of digital medical devices, diagnostics and services. In a speech to the European Parliament, the European Commissioner for Health and Food Safety, Stella Kyriakides, stressed the importance of empowering citizens to manage their own health care, as set out in the 2018 European Commission Communication regarding digital transformation of health and care in the Digital Single Market. She talked about the potential for digitalisation "to provide cost-effective high-quality healthcare whilst reducing inequalities". The goals are to ensure that patients have access to their data; that their data remain confidential; and, that information systems integrity is protected.[3] This objective was also underlined in the recent European Parliament resolution on enabling the digital transformation of health and care.[4]

Patient empowerment is an important goal of EmERGE. It was found that the co-design process empowered people living with HIV to become involved in the development of the EmERGE app and to become activated in advocating for functionalities (EmERGE Deliverable 2.3). Empowerment is an important emerging concept in health and limited evidence exists linking empowerment to more rational and cost-effective usage of health services and improved adherence in certain chronic diseases. However, empowerment is a concept without a universal definition, nor a commonly accepted mechanism for measuring it (Cooper et al. 2019). Patient-reported outcome measures (PROMs) linked with health service delivery outcomes are becoming increasingly important (Barr et al. 2015). mHealth implementation can lead to improved patient empowerment; however, it will be important to identify effective measures to assess the impact of digital solutions on empowerment.

Digital health solutions have the potential to help decrease inequality in healthcare access. In the UK, it was shown that young people and ethnic minorities found online STI services acceptable and appreciated the speed, convenience and privacy that they provided (Aiken et al. 2016a). Another UK study showed that those at higher risk – young people, men who have sex with men, and those engaged in finding sexual partners online – were more likely to use the internet for sexual health purposes (Aicken et al. 2016b). A study in China found that men who have sex with men prefer using their mobile devices for sexual health information and services, with their main concern being confidentiality, which might be a problem for that particular context (Muessig et al. 2015).

Section 2 looks at opportunities and challenges for adoption at the health system and clinic level, including the ways in which EmERGE was able to anticipate some of the challenges *a priori* as part of the project design. Unanticipated challenges or those that required action at the time of implementation are also described.

Section 3 highlights the opportunities and challenges of implementation at the user level, outlining the experiences of clinicians and patients.

Section 4 describes how EmERGE addressed opportunities and challenges to innovation and development.

The project builds on prior knowledge, user demands and feedback, as well as experience acquired during the course of the co-design and the implementation study to support the rolling out to other sites and possible transfer to additional clinical sites.

[3] https://ec.europa.eu/commission/commissioners/2019-2024/kyriakides/announcements/intervention-commissioner-kyriakides-european-parliament-plenary-digital-transformation-health-and_en

[4] European Parliament resolution of 18 December 2019 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2019/2804(RSP)). https://www.europarl.europa.eu/doceo/document/TA-9-2019-0105_EN.html

2.0 Opportunities and challenges for adoption at health system and clinic level

2.1 General

mHealth innovations are widely known to present opportunities for health systems across many domains, including cost savings, improved efficiencies, and better data management for clinical and research purposes (Cooper et al. 2017).[5,6] Some challenges in implementing new mHealth interventions include the complexity and political nature of health systems decision-making; trust among various stakeholders; the nature of relationships between community and the clinic; and, whether or not the mHealth intervention is commercialised as a for-profit versus a non-profit enterprise (EmERGE Deliverable 2.3; EmERGE Deliverable 2.4).

The EmERGE project addressed a number of these anticipated challenges through its design and implementation as a co-design, research and technology scale-up project. The co-design aspect of the project fostered buy-in from stakeholders, particularly users (clinicians and patients). Through careful involvement of end users and careful analysis of iterations of the mobile device application, EmERGE was able to identify, anticipate and manage technology development issues and concerns throughout the project. That said, there was a significant evaluative burden on participants in EmERGE because of the research component of the project. The following sections look at specific challenges and how EmERGE was able to manage them.

2.2 Costs

EmERGE, as a 5-year project, came with funding to support stakeholders at all levels: health clinics, clinicians, patients, patient groups and researchers. These funds ensured that partners were able to allocate significant time to the project and prioritised EmERGE activities. This helped to create buy-in to the project and to free up necessary time to participate in its processes.

mHealth interventions often promise to improve communication between patients and their caregiver, decrease costs, improve efficiencies and support better medical clinic management.[6,7]. However, in terms of promoting mHealth interventions, there is a lack of evidence based on accepted implementation research standards, i.e., evidence to show efficacy, effectiveness, dissemination research and costs (Tomlinson et al. 2013).

Most mHealth interventions, including EmERGE, focus on stable HIV patients. However, it has been shown that even in unstable patients mHealth can be beneficial. One Canadian study found that investment in SMS-based adherence services for vulnerable patients identified and solved problems, helping them become more stable and achieve undetectable viral loads,

[5] https://www.medicalnewstoday.com/articles/322865.php#10
[6] https://www.mobindustry.net/does-it-hurt-or-does-it-help-5-pros-and-4-cons-of-mhealth-for-doctors-and-patients/
[7] https://kaysharbor.com/blog/healthcare/8-mobile-device-benefits-in-healthcare

thereby contributing to the prevention of new HIV infections and improved self-reported quality of life measures. Cost modelling showed that this was achieved at a reasonable cost, compared to lifelong antiretroviral therapy for those who would have become HIV-infected (Campbell et al. 2018).

The EmERGE project clinical sites reported various issues regarding costs. In most cases, EmERGE provided an alternate care pathway that helped to reduce clinic time for both the patient and the clinician, which freed up time for the clinician to address other issues, including manage persons living with more complex HIV. However, this does also depend on the nature of the healthcare system. For instance, one country's site reported that, because reimbursement is linked with face-to-face appointments at the clinic, EmERGE implementation has resulted in decreased revenues for physicians and the clinic itself.

It is important for transferability and scale-up to ascertain the added value of the app, including costs. Yet, cost-savings calculations are complex and, therefore, need to take into consideration both financial costs, opportunity costs and externalities or non-financial added value, as well as direct development and implementation costs.

These changes have reduced, to varying degrees, the annual cost of HIV outpatient services in each of the sites. The reduction of outpatient visits has led to a reduction of outpatient services costs that varied between 6% to 33% (EmERGE Deliverable 3.4 2020). Although these savings are small compared to the high cost of antiretroviral treatment, these findings are notable. For the EmERGE project, only people who were medically stable were included. The use of clinical services in this population was relatively low to begin with, but despite this, cost-savings were identified. A limited number of participants were included in the EmERGE project and, as such, the overall savings that are potentially achievable for each clinic with increased number of people living with HIV using the app could be greater.

Two opportunities exist to realise these greater cost savings. First, with the expansion of EmERGE implementation in existing and new sites outside of a rigid investigational protocol, an increased number of stable patients will benefit from the app, freeing more time up for clinics to manage more complex patients, presumably reducing costs associated with poor health outcomes in those particular patients. Secondly, there is an opportunity for the EmERGE pathway to be used by patients with more complex HIV disease or comorbidities themselves, which could result in significantly more relative cost savings. Because the primary goal of EmERGE is to provide choices to patients and clinicians by offering an alternative care pathway, those patients who choose to use the app will end up freeing up clinic time for those for whom the app is unsuitable or for those whose preference leans towards face-to-face interactions with healthcare professionals in their clinics.

2.3 Technology and Security

Experience with mHealth interventions has led to improved data management. This includes more seamless data flow, the opportunity to aggregate data, and to provide deep insights into the data.[6,7,8] However, the implementation of new technologies can be costly and complex. EmERGE managed these challenges by allocating sufficient funds and time for IT staff to be able to work with sites to address technological issues.

[8] https://mhealthintelligence.com/news/the-benefits-of-mobile-health-strategies

EmERGE worked in a decentralised manner that acknowledged the strengths and challenges at the local level and provided bespoke solutions for adapting the EmERGE technology. One of the main concerns for users was data protection and, therefore, EmERGE carried out background assessments at each site to establish current data protection legislation and practice. The data security was an inherent part of the EmERGE technical architecture but integration with hospital systems required compliance with site-specific hospital IT requirements.

The challenges in integrating EmERGE with existing systems differed by site. It took longer to integrate EmERGE in sites with complex IT systems. It was easier to integrate EmERGE in sites with dedicated and involved IT personnel, as opposed to just clinical staff.

2.4 Interaction with other health record systems

Clinics participating in the EmERGE project had electronic patient record systems, in the form of local clinical databases already in place. This is not the case for all HIV clinics in EU countries and therefore capacity to convert paper record systems to electronic systems is a potential implementation barrier. Most local clinical databases do not allow patients to access the medical record. mHealth-based technology developments enable access however, mHealth initiatives are often closed systems, meaning that they refer to one health condition or aspect of health care only, forcing patients to use multiple apps for different purposes (Tomlinson et al. 2013).

During the course of the EmERGE project, national portals for enabling patient access to medical data became live or else plans to develop portals were published. The question of whether these systems take away the need for mHealth is an important one. For people living with comorbid health conditions accessing all health results can be beneficial. It would be useful to investigate the utility of mHealth in supporting people to stay engaged with clinics and their healthcare.

Respondents from key informants from the EmERGE project indicated that most users would prefer one integrated system. An app that acted as a one-stop shop for all of a person's health needs would be helpful to manage appointments, health-related information and laboratory results for HIV and other co-morbidities. A major factor in determining whether patients wanted a combined or separate system for HIV results was patients' experience with stigma and self-stigma in a particular country. Where stigma and discrimination against people living with HIV is high, people feel that their data is safer when stored in a separate system.

2.5 Recommendations: Health systems and clinics

- Include non-monetary and opportunity costs into calculations of cost-effectiveness. HIV treatment will remain the costliest aspect of HIV care. mHealth interventions will provide added value in important areas other than direct programme costs.
- On initiation of the project, invest in partnerships with clinics, users and other stakeholders in order to achieve consensus and buy-in.
- Where possible, secure funding ahead of time to help free up stakeholders' time and to be able to anticipate and address technical challenges. Where *a priori* funding is not feasible, leverage the partners to work together to find funds together.

- Anticipate technological change, especially with respect to alternative and competing systems. As part of assessments with stakeholders, determine the added value of a separate HIV app and how it fits within or beside other national or clinic-based systems.

3.0 Opportunities and challenges for adoption of user (clinician or patient) level

3.1 General

Advantages of mHealth interventions include better health outcomes due to improved access to health information and adherence to treatment.[6,8] Improved adherence has been found even in very unstable patients (Campbell et al. 2018).

The EmERGE project enrolled 2251 individuals between April 2017 and October 2018 who were followed up for between 12 and 30 months.

Uptake varied by site and was good: two sites enrolled approximately 25% of their cohorts to the study (25.8%; 24.2%) which was as anticipated. One site enrolled more individuals (47.4% of the clinic cohort), while two sites enrolled fewer (8.4% & 10.0%).

Clinical outcomes remained good in this medically stable population: 99.6% had an undetectable HIV viral load at 12 months of follow up. No serious adverse events related to the pathway or platform were reported.

As part of the study, questionnaires were completed at baseline, 12 and 24 months. These included measures of patient activation (PAM-13) and Quality of Life (EQ5D5L & PROQOL-HIV). In this medically stable population patient activation scores were high; similarly, QOL measures scored highly in all domains. The lowest scores were seen in domains reflecting mental health issues and stigma. These scores were maintained from baseline to 12 months. (Whetham et al. 2019, EmERGE Deliverable 6.2)

3.2 Clinicians

According to EmERGE reports and key informants, the most significant benefit to clinicians resulting from the implementation of EmERGE was the increase in time that clinicians had to devote to some of their patients. In many cases, clinic visits dropped to only once per year, with other visits supported by data provided through the app. This increased time allowed physicians to spend additional time with those with more complex needs. EmERGE has the potential to help manage capacity in sites where the numbers of patients continue to increase. The introduction of PrEP in health facilities increases the demand on clinical resources, especially the time of healthcare providers. EmERGE has the potential to increase the capacity of clinics to be able to address the needs of people using PrEP.

However, one site reported that EmERGE created extra work for HIV nurses because it required manual input of data from an existing clinic system into the EmERGE web-based clinic platform.

Some clinicians indicated that they missed the human interaction with patients, especially those whom they have known for a long time. One individual indicated that, while he missed these social interactions personally, he did not miss them from a medical perspective. He was

secure in the quality of care that his patients were receiving and was grateful for the extra time he was able to devote to people whose care required more of his attention.

Two clinics participating in the EmERGE project experienced local barriers to adoption whereby the colleagues of EmERGE HIV physicians were reluctant or refused to participate in the project. Reasons for this included lack of financial reimbursement, a preference for not using technology and an understanding that seeing the patient is fundamental to care.

3.3 Patients

mHealth technologies that are beneficial to patients must address the following characteristics: usability, interoperability, data security and privacy, network access and reliability (Bradway et al. 2017). When successful, these interventions benefit patients by providing time savings (fewer visits to the clinic); better access to and ownership of their health data; graphics to illustrate their clinical progress; features to check drug interactions; and the location of nearby pharmacies (Vervier et al. 2019). Digital technologies have been found to support self-management and adherence to treatment (Catalani et al. 2013; Clayborn et al. 2015).

Barriers include technical issues, such as access to internet networks and availability of mobile devices, which varies according to demographics, including where one lives and the extent to which a demographic group is marginalised or vulnerable (e.g. LGBT people) (Makri 2019). Security, privacy, consent and unwanted monitoring by external third parties are issues that must be addressed in the implementation of mHealth interventions (Vervier et al. 2019). As already mentioned, patients are often faced with multiple, mutually exclusive technological applications that support various aspects of their care (Tomlinson et al. 2013).

While digital technologies provide additional information to patients, not all of them have the ability to interpret this information (Vervier et al. 2019). Health literacy is important in the context of mHealth and implementers should consider the ability of sub-groups of patients (stable, newly diagnosed, low literacy, people with a migration background) to understand the data presented to them.

From the EmERGE programme itself, there are a lot of data outlining the opportunities and challenges. Most of it is formative in nature because of the project's co-design orientation. However, these data are rich with impressions from patients regarding the utility of the app.

Opportunities – Evidence from Project Reports and Key Informants

EmERGE demonstrated that co-design can enhance empowerment by providing patients with the opportunity to engage with clinicians, project personnel and researchers as equal players in a process (EmERGE Deliverable 2.4 2020). Patients indicated that they could voice their needs for the first time in a safe environment and they felt that they were heard. The co-design approach gave people confidence to speak up about their needs, both from a clinical and technological perspective. In addition, people living with HIV indicated that the EmERGE project stimulated them to further investigate the digital health field.

The EmERGE project has shown to be beneficial to patients who have identified the usefulness of having ownership of all their data in one place. It provides them with all the information they need and gives them a sense of ownership of those data and the confidence to use them. The results can be shared with other healthcare providers, including the general practitioner, or with friends and family. One site mentioned that the accessibility of the data allows them to show partners, family members and friends that they are healthy and doing

well with their HIV disease. Another site mentioned that the app is being used by patients to negotiate sexual relationships with their partners by highlighting that they are, indeed, have an undetectable viral load and are, therefore, not able to pass on the virus.

A significant benefit, according to patients, is time savings. Most patients using EmERGE are able to reduce the number of visits to the hospital. They receive their results via the app and, in the near future, will use built-in chat or video calls to ask questions of their healthcare providers. In addition to reducing the number of trips to the clinic, the time at the clinic itself is shorter due to decreased waiting times. One site indicated that, because there is only one HIV treatment facility in the country and people must travel long distances, many people benefit from time savings because of the app.

Patients have noted that EmERGE provides a secure environment for them to manage their HIV care. The app provides a level of security that regular email and telephone calls do not. Some patients have pointed to the elimination of paper-based results as a way in which their data remain private.

Challenges – Evidence from Project Reports and Key Informants

Some patients indicated that they missed interactions with their clinicians, indicating that the personal contact is important to them and that their general practitioners do not have the required specialised knowledge. Some feel that the decrease in clinical visits leads to a very impersonal interaction, lacking the human touch.

It was acknowledged that EmERGE does not contain all of a patient's results, whereas national or clinic systems contain all of the results entered by the laboratory. Physicians at each site determine what is entered into EmERGE and some patients do not appreciate what they see as gatekeeping. There is also a lack of a full treatment history, where results go back further than 10 years, but this could due to those records not existing in electronic format in some locations.

Most sites indicated the desire for the EmERGE app to be a place where comprehensive information about their health is stored, and not just their HIV-related information. People want to be able to manage their health in general and not just their HIV. An exception was one site where they indicated that people are satisfied with EmERGE because it gives them a separate platform from the national one, preventing other healthcare providers from finding out their HIV status and potentially discriminating against them because of it.

Many sites mentioned missing functionalities on the app but these differed by site. Some examples include appointment management, two-way interactions with healthcare professionals and management of medication refills. One site mentioned that it will be important for EmERGE to include these and other functionalities in the future in order to meet the technical expectations of people living with HIV as app users, including badge notifications of new messages and updates. However, one site indicated that people were concerned that message notifications could spark curiosity in friends, or other people around them who do not recognise the app icon when it pops up.

The importance of health literacy was mentioned by several sites who, while grateful for access to their health data, are concerned that some individuals might not have the knowledge or skills to be able to interpret these data. Potential solutions mentioned included pop-up information windows or links to recognised internet-based sources of information. Most sites recognised that the availability of information does not automatically lead to a better

understanding of one's health situation. One site described how EmERGE has nurtured curiosity among users to learn more information about their HIV disease and treatment.

The ability to choose to use EmERGE or not is critical. Some people want to be actively involved in their HIV disease management, while others just want to go on with their lives. For the former, there are those who prefer face-to-face interactions and those who would rather use technology. EmERGE gives them options to suit their health seeking behaviour preferences. A potential barrier to the adoption of mHealth could be the perception by patients that its primary purpose is to reduce costs by moving them onto remote management of their condition. It is essential that patients see mHealth products as interventions that add options for managing their health and do not replace their access to healthcare providers.

Sites indicated that they were keen to see evidence that EmERGE has a positive impact on the quality of life of people living with HIV. This is important for them to convince those who are reluctant to embrace new technology to get buy-in. It will be important to investigate this further.

Site-specific issues included the following:

- One site indicated that people were reluctant to participate in the EmERGE project because of HIV-related stigma and discrimination. People were afraid to be identified as being HIV-positive and were worried that their privacy would be breached. This initial fear was mitigated by the co-design approach.
- One site indicated that access to technology was a challenge for some people. In that country, there is sometimes limited connection to internet networks in some regions. Most people have mobile telephones, but some do not have smartphones, making it impossible to use EmERGE.
- One site indicated that the time saved is minimal because the HIV care pathway in the country forces people to go to the clinics for bloodwork, consultations and medicines. The added value of EmERGE is not clear to patients who still must spend their time to travel and take time off work. It will be important for EmERGE to provide evidence of its added value in order for people to be willing to adopt the app.

3.4 Recommendations: Users

- Utilise a co-design approach in order to bring together stakeholders, reduce power inequalities and empower patients.
- Implement mHealth interventions in a decentralised manner, taking into consideration local capacity, as well as the needs and restrictions of local users. This includes important issues related to HIV-related stigma and discrimination.
- Implement measures to improve health literacy among users of mHealth technologies, by embedding functionalities in the app and/or engaging with patient groups (people living with HIV networks).
- Further investigate the utility of mHealth in supporting people to be empowered to engage more meaningfully in their own health care, including being better connected to their healthcare workers between appointments.

4.0 Opportunities and challenges: innovation and implementation

4.1 Funding

The demand for HIV services is currently still expanding; however, the goal in many countries is to realise zero new infections, which will decrease demand. Already there is a decline in infections in countries in the EU, particularly among MSM, due to earlier diagnosis and treatment and, in some countries, the introduction of PrEP (ECDC and WHO Europe 2018). HIV as a public health threat is diminishing, resulting in a reduction in HIV-specific funding.

In some countries, however, the number of new infections continues to rise. In addition, clinics are facing a new challenge with the introduction of PrEP, where, in many countries, the management of antiretrovirals for HIV prevention occurs in the same clinics as treatment of HIV infection. Therefore, EmERGE has the potential to increase the capacity of clinics to manage increasing numbers of patients and PrEP users.

Efforts to make HIV treatment and care more affordable will remain attractive to healthcare system funders, third-party insurers, commercial entities and bi- and multi-lateral donors. It is important to note, however, that the most expensive component of a person's HIV disease management remains the cost of medicines. In order to justify yet more spending on HIV, innovation projects must identify other ways to measure added value, including time savings for patients and clinicians, better management of difficult cases, improved health outcomes and improved quality of life for patients. They have to show how they contribute to improving health system performance and responsiveness.

New technology projects in healthcare thrive in conditions, such as seen in the implementation of EmERGE, that are bottom-up and processes driven by new effective technology (Braithwaite 2018). EmERGE was successful, in part, because it secured public funding for stakeholder participation, which reduced several of the anticipated challenges associated with technology innovation in healthcare.

4.2 Stakeholders

Trust is a key issue when working to innovate new technological healthcare solutions, especially with people living with HIV who are subject to stigma and discrimination. Most digital health solutions are purely commercial. One of the strengths of EmERGE is that it is value based, participatory and focussed on quality. The fact that this was an EU project that was clinically led built trust among stakeholders. The diversity of non-commercial partners added to this trust. Co-design ensured that partners felt that they were part of the development and integral to the implementation. Initially, the EmERGE project envisioned a legacy where the application would be commercialised as a for-profit product. However, engagement with stakeholders has led to a decision to move forward with EmERGE as a not-for-profit platform, which was instrumental in building trust among clinics, clinicians and patients. The investment in stakeholder relationship building can assist with the long-term sustainability, scale-up and evolution of the app.

4.3 Timeline

The advantage of investing in a long-term project is that it is possible to build relationships and accommodate individual local needs of partners. With a multi-country intervention, it is essential to have the time to address complexity in a variety of situations.

4.4 Technology

Five years is a long time in terms of technology development. One of the sites indicated that, during the project implementation, systems were developed that competed with EmERGE. In the fast-changing world of technology development, it is important that a platform remain agile to adapt to changes as they occur.

4.5 Recommendations: Funders, Product Developers, Clinics and Patient Groups

- Funders should anticipate the need for sufficient funding for all parties in order to compensate for time spent to adapt and implement the mHealth intervention.
- Product developers and clinics should provide financial and non-financial evidence of the added value of implementing mHealth interventions from the perspective of the institution, the clinician and the patient.
- Product developers should invest in stakeholder relationship building form the start and embrace a co-design approach to developing and implementing mHealth innovations.
- Product developers should weigh the importance of investing in time to develop relationships among stakeholders while remaining impactful in a fast-changing environment in technologic development.
- People living with HIV networks and organisations should advocate for mandatory involvement in mHealth initiative development, scale-up and transferability to other areas.

References

Aicken, R.H.C., Fuller, S.S., Sutcliffe, L.J., Estcourt, C.S., Gkatzidou, V., Hone, K., Tariq Sadiq, T., Sonnenberg, P. and Shahmanesh, M. (2016). Young people's perceptions of smartphone-enabled self-testing and online care for sexually transmitted infections: qualitative interview study. *BMC Public Health* 16:974. (https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/s12889-016-3648-y)

Aicken, C.R.H., Estcourt, C.S., Johnson, A.M., Sonnenberg, P., Wellings, K., and Mercer, C.H. (2016). Use of the internet for sexual health among sexually experienced person aged 16 to 44 years: evidence from a nationally representative survey of the British population. *J Med Internet Res* 2016;18(1):e14.

Barr, P.J., Scholl, I., Bravo, P., Faber, M.J., Elwyn, G., McAllister, M. (2015). Assessment of Patient Empowerment - A Systematic Review of Measures. *PLoS ONE* 10(5): e0126553. doi:10.1371/journal. pone.0126553.

Braithwaite, J. (2018). Changing how we think about healthcare improvement. *BMJ* 361:k2014.

Bradway, M., Carrion, C., Vallespin, B., Saadatfard, O., Puigdomènech, E., Espallarguesm, M., Kotzeva, A. (2017). mHealth assessment: conceptualization of a global gramework. *JMIR Mhealth Uhealth* 5(5): e60. doi: 10.2196/mhealth.7291

Campbell, A.R., Kinvig, K., Côte, H.C.F., Lester, R.T., Qui, A.Q., Maan, E.J., Alimenti, A., Pick, N., Murray, M.C.M. (2018). Health care provider utilization and cost of an mHealth intervention in vulnerable people living with HIV in Vancouver, Canada: prospective study. *JMIR Mhealth Uhealth* 6(7):e152. doi:10.2196/mhealth.9493

Cooper, V., Clatworthy, J., Whetham, J. and EmERGE Consortium. (2017) mHealth interventions to support self-management in HIV: a systematic review. *The Open AIDS Journal* 2017;11:119-132.

Cooper, V., Clatworthy, J., Harding, R., Whetham, J. and EmERGE Consortium. (2019). Measuring empowerment among people living with HIV: a systematic review of available measures and their properties. *AIDS Care* 31(7):798-802. doi: 10.1080/09540121.2018.1537464

EmERGE Deliverable 2.3. (2020). Workpackage 2: Sociotechnical evaluation and co-design. D2.3 Final evaluation report. Best practice in co-design and user (clinician and patient) involvement across study sites. (in progress)

EmERGE Deliverable 2.4. (2020). Policy and practice guidelines: Report on guidelines to support co-design for improved usability, acceptability and patient outcomes in mHealth developments. (in progress)

EmERGE Deliverable 3.4. (2020). Cost-efficiency of the mHealth Pathway at the Five EmERGE Sites (in progress))

EmERGE Deliverable 6.2 (2020) Report on patient empowerment and quality of life analyses.

European Centre for Disease Prevention and Control, WHO Regional Office for Europe. (2018). HIV/AIDS surveillance in Europe 2018 – 2017 data. Copenhagen: WHO Regional Office for Europe.

Frontline AIDS. (2019). Quality of life for people living with HIV: what is it, why does it matter and how can we make it happen? (https://frontlineaids.org/wp-content/uploads/2019/02/quality_of_life_briefing_final_original.pdf)

Makri, A. (2019). Bridging the digital divide in health care. *The Lancet Digital Health* 1(September):e204-e205. (https://www.thelancet.com/action/showPdf?pii=S2589-7500%2819%2930111-6)

Muessig, K.E., Bien, C.H., Wei, C., Lo, E., Yang, M., Tucker, J.D., Yang, L., Meng, G., Hightow-Widman, L.B. (2015). A mixed-methods study on the acceptability of using eHealth for HIV prevention and sexual healthcare among men who have sex with men in China. *J Med Internet Res* 17(4):e100. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420841/?report=printable)

Tomlinson, M., Rotheram-Borus, M.J., Swartz, L., Tsai, A.C. (2013) Scaling Up mHealth: Where Is the Evidence? *PLoS Med* 10(2): e1001382. doi:10.1371/journal.pmed.1001382

Vervier, L.S., Calero Valdez, A., Ziefle, M. (2019). "Attitude"-mHealth apps and users' insights: an empirical approach to understand the antecedents of attitudes towards an mHealth application. In *Proceedings of the 5th International Conference on Information and Communication Technologies for Ageing Well and e-Health* (ICT4AWE 2019): 213-221 ISBN: 978-989-758-368-1 doi: 10.5220/0007720002130221

Whetham, J., Jones, C., Bremmer, S., Leon, A., Begovac, J., Apers, L., Borges, M., Zekan, Sl, Teofilo, E., Garcia, F., and on behalf of the EmERGE Consortium. Feasibility, uptake and acceptability of the EmERGE mHealth app in individuals living with stable HIV in five European countries. (2019). *EACS. 17th European AIDS Conference.* (https://onlinelibrary.wiley.com/doi/epdf/10.1111/hiv.12814)

World Health Organization. (2016). Framework on integrated, people-centred health services: Report from the Secretariat. *Sixty-ninth World Health Assembly* Provisional Agenda Item 6.1. 15 April 2016. (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_39-en.pdf?ua=1&ua=1)

World Health Organization. (2019). WHO consolidated guideline on self-care interventions for health: sexual and reproductive health and rights. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO. (https://apps.who.int/iris/bitstream/handle/10665/325480/9789241550550-eng.pdf?ua=1)