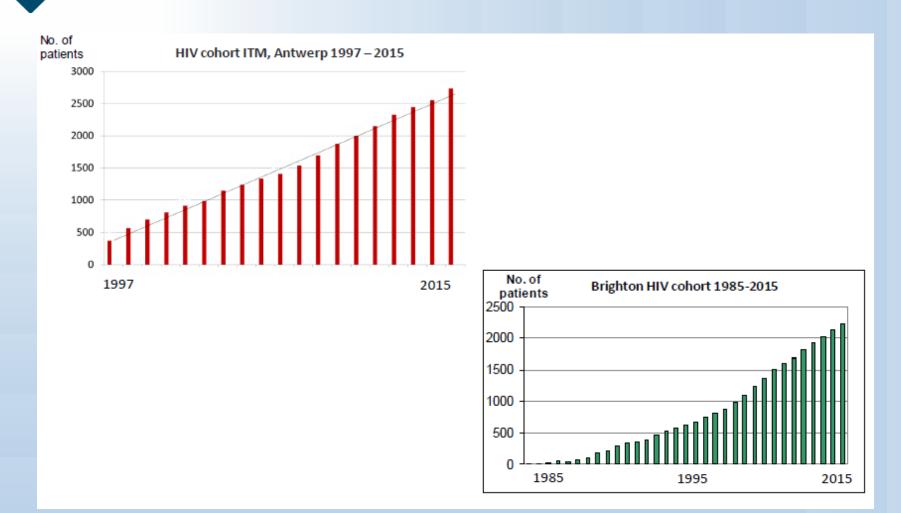
# The EmERGE project: the result of a changing disease in a changing world

## BREACH conference 2016, Charleroi Ludwig Apers ITM



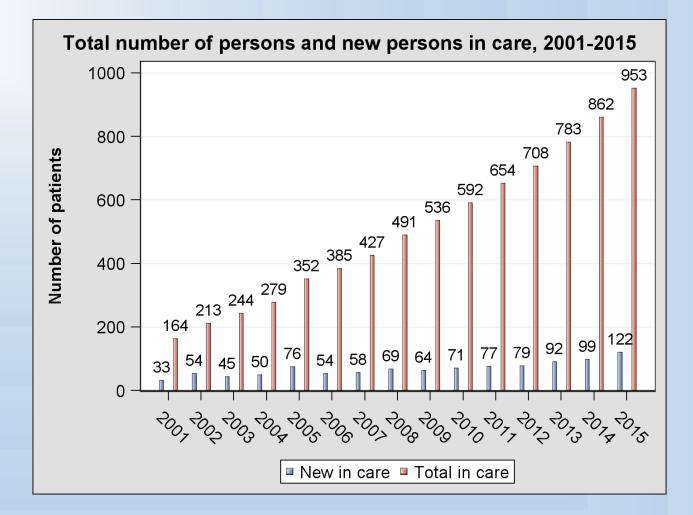
Institute of Tropical Medicine | Clinical Sciences

## Prolonged life expectancy, decreased mortality: ever increasing numbers of patients





### Zagreb HIV cohort 2001-2015

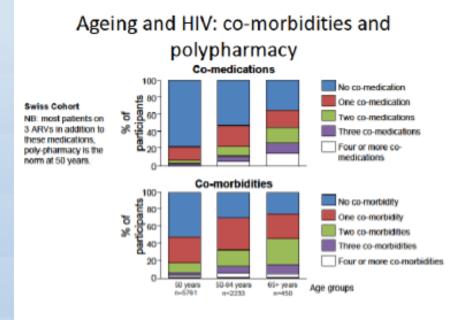




## Ageing and frailty: changing morbidity

Reduced complexity of HIV control

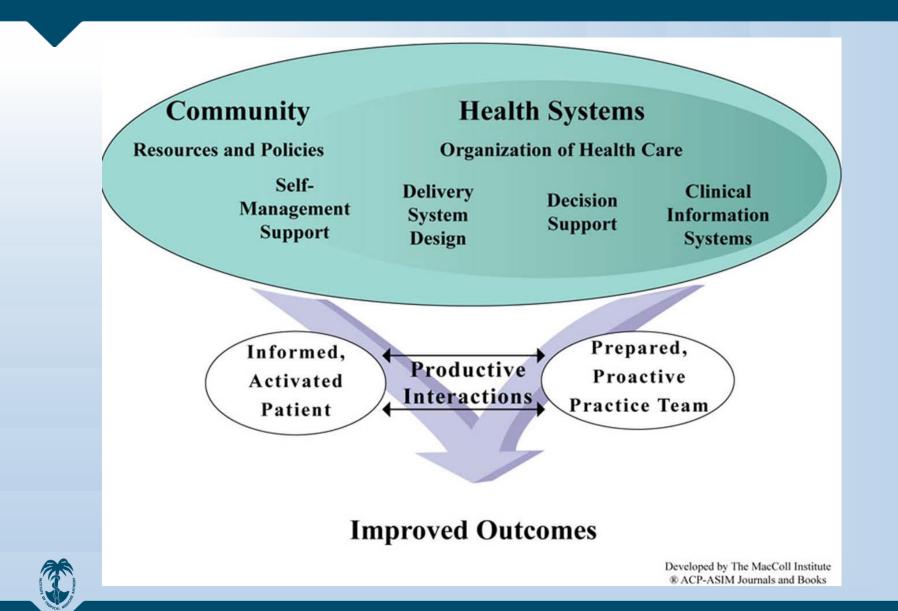
Increased number of comorbidities and polypharmacy





Hasse B. et al. CID 2011:53: 1130-1139

## 'the chronic care model' (eg. KCE report 2012)





## Belgian contect: action plan e-health - MoH





Evaluating mHealth technology in HIV to improve Empowerment and healthcare utilisation: Research and Innovation to Generate Evidence for personalised care

European Union's Horizon H2020 research and innovation programme: Grant Agreement No 643736 Five year project: May 2015 - April 2020

> This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 602108



### Five clinical sites:

- Antwerp
- Brighton
- Barcelona
- Lisbon
- Zagreb

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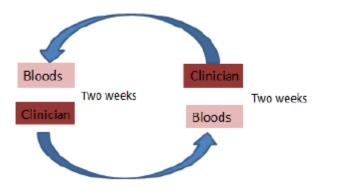
## **Objectives**

- i. To develop a novel mHealth platform for use by 3,900 patients with stable HIV infection in five different European settings – platform developed, integrated and piloted by M18
- *ii.* To validate acceptability, usability and effectiveness of the mHealth platform in routine HIV patient clinical management validation study completed by M54
- iii. To assess the impact of the mHealth platform on patient self management and empowerment – study powered to demonstrate improvement in patient empowerment
- *iv.* To analyse cost, cost effectiveness or cost saving associated with installing the mHealth platform in participating health systems health economic analysis integral part of work plan, completed by M54
- v. To valorise the outputs of the work via a consortium centred value chain and business plan to promote and implement the mHealth platform in various European healthcare settings as a sustainable, effective, safe and economic modality for HIV care

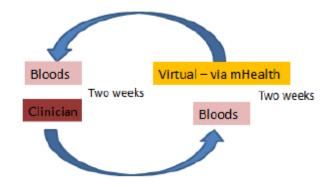




## Concept



Person living with stable HIV seen twice a year for routine follow-up, usually with blood samples drawn two weeks prior to clinician appointment



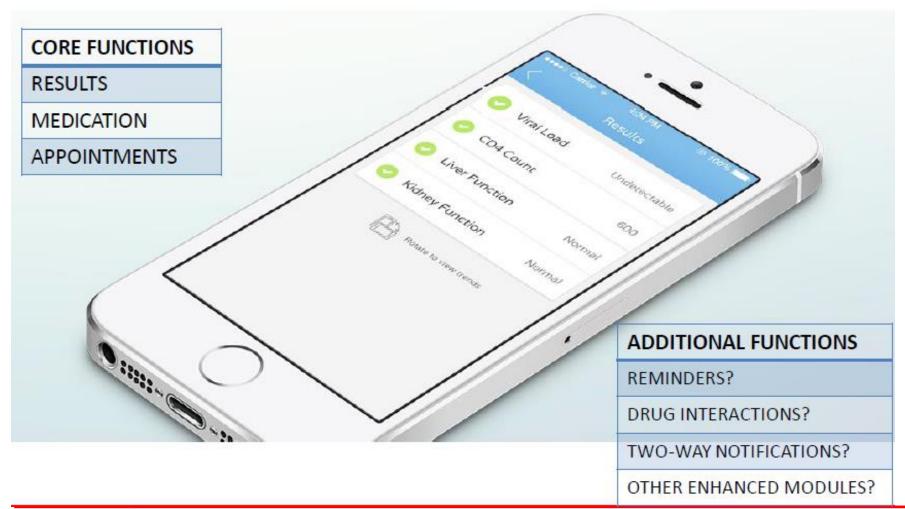
Proposed EmERGE pathway – seen routinely once a year with interim visit carried out via mHealth platform

- \*Results checked by a clinician \*Pushed through securely to 'App' with medication info & future appt
- \* Prescription issued
- \* Option to pause if any problems





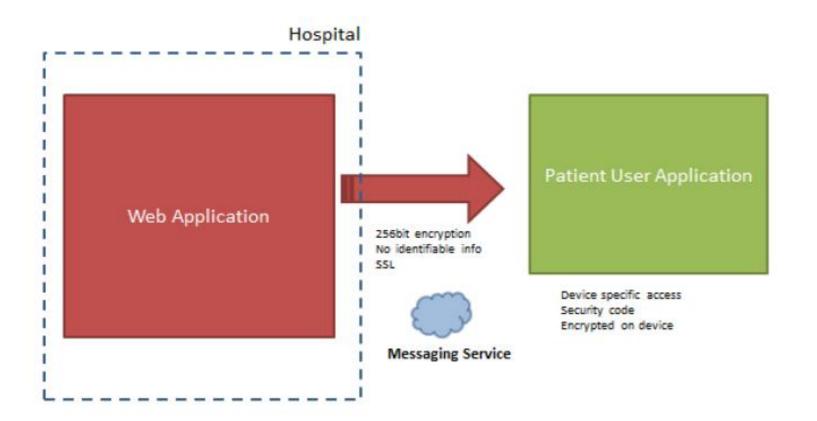
















### Work stream 1 - Development and integration of the mHealth platform WP1 – Situational Analysis and Background Assessment

WP2 - Co-Design and Sociotechnical Evaluation WP4 – Platform Development, Testing and Deployr

Work stream 2 – Validation Study WP3 – Health Economics WP5 - Implementation and validation study WP6 – Quantitative Patient Outcomes



Institute of Tropical Medicine, Antwerp

Work stream 3 – Innovation, Exploitation and Dissemination WP7 – Innovation and Exploitation WP8 – Dissemination WP9 – Project Management





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**University of Brighton** 



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FCRB, Barcelona



**BSUH**, Brighton



London



## Validation study

A large (3808 patients) prospective cohort study, undertaken in five European sites to validate an mHealth platform to enable self-management of HIV in patients with stable disease using a tailored HTA process, Model for Assessment of Telemedicine Applications (MAST), specifically developed for the assessment of mHealth solutions.

As site recruitment will be sequential and the recruitment period will last 18 months at each site, a maximum followup 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.



#### INCLUSION CRITERIA

1. Documented HIV positive; Age > or = 18 years of age; Able to give informed consent

## 4. In possession of a smartphone, tablet, or similar technology supporting the mHealth platform

5. Stable on ART

ART should be unchanged for at least 3 months, and viral load undetectable for at least 6 months.

#### 6. Clinically stable from an HIV perspective

- a) No opportunistic infection within the previous 12 months
- b) No current HIV-related illness requiring ongoing treatment or monitoring

#### **EXCLUSION CRITERIA:**

- 1. Aged less than 18 years, Pregnant
- 2. Participating in a clinical trial or receiving an investigational medication
- 3. Unable to comprehend the patient information sheet; to comprehend the instructions for using the mHealth platform
- 4. Considered for any other reason by their regular physician to be unsuitable for study participation





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## **Critical perspectives**

## Substitution of face-to-face visit

- Several clinicians highlighted that information and advice for patients is constructed in dialogue and also based on physical examination of the patient
- Many PLWH stated that they want to see their HIV clinician at least every 6 month; they emphasized that in this consultation they can discuss also emotional and social aspects related to HIV
- Therefore, several participants argued that patients should have the option whether they want a face-to-face visit or manage their health via an app





### ... work in progress...

## Thank you

