EmERGE project: Key Findings

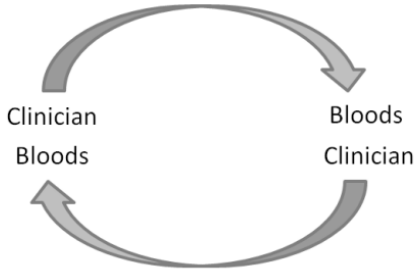
Dr Jenny Whetham
on behalf of the EmERGE consortium

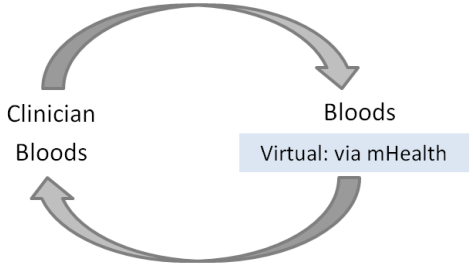
https://www.emergeproject.eu/

May 2015 – April 2020

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under Grant Agreement No. 643736

EmERGE Concept





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

EmERGE pathway – person 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

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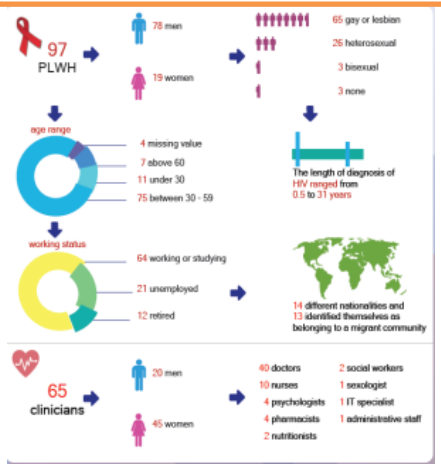
Background assessment

EACS 2017: PE26/5 Ludwig Apers

Co-design & sociotechnical evaluation



Marent et al, JMIR mHealth U Health 2018: 19:6:e184
Marent et al, Soc Sci Med 2018: 215: 133-141

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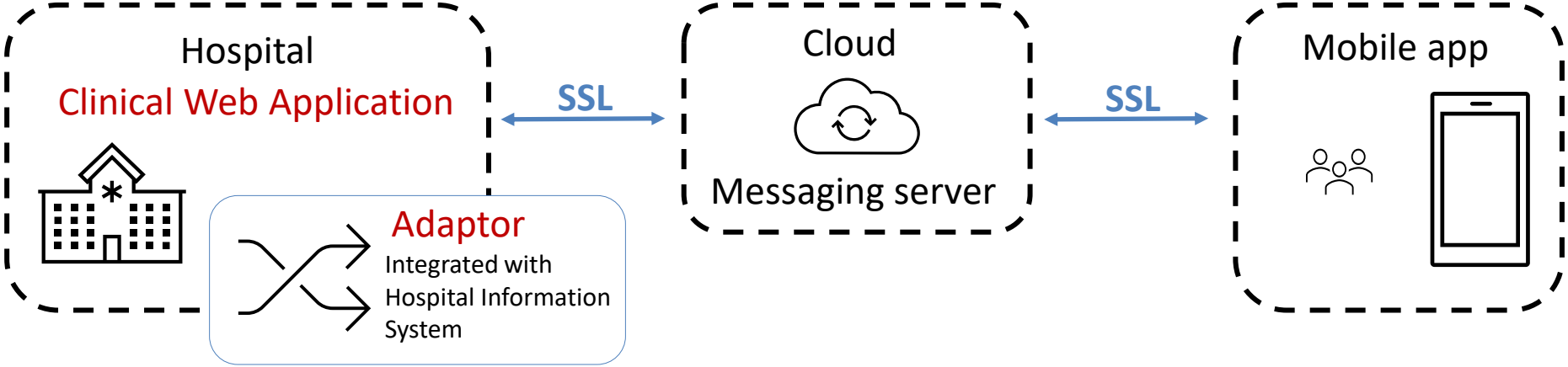

EmERGE Platform

Chausa, P et al, MEDICON, 2019

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Methods

- Prospective cohort study
- Pre-post design

m0 m12 (m24)

Feasibility & uptake / use
Patient experience
Potential effectiveness
Maintenance of quality of care
Cost minimisation

Study inclusion criteria:

1. *Documented HIV infection*
2. *Aged at least 18 years old*
3. *Able to give informed consent*
4. *In possession of a smartphone, tablet or similar technology supporting the mHealth platform*
5. *Clinically stable on ART**

** ART for at least 1 year; unchanged for at least 3 months; 2 undetectable VL <50 copies / ml, no current pregnancy; without any new WHO clinical stage 2, 3 or 4 events within 12 months [adapted from WHO criteria Waldrop 2016)*

Patient activation (PAM-13)
Quality of Life (EQ5D5L; PROQOL-HIV)
Adherence (M-MASRI)
Patient experience (PREM)
System usability (SUS)

HIV specific PROM *Positive Outcomes: Bristowe et al HIV Med 2019;20:542-554*
Successful ageing (FRAIL)

Micro-costing studies at each site
Unit and annual costs calculated in national currencies > 2018US$ PPP
Costs linked to mean per patient year (MPPY) use of OP services
Date collected 12m prior & 12m after introduction of EmERGE
Outcomes: VL; CD4; PAM-13; QOL
Out of pocket expenditure

*Model for assessment of telemedicine applications: **MAST***
Kidholm K, Int J Technol Assess Health Care 2012:28(1):44-51

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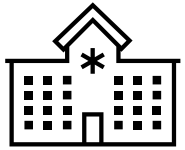

5 2251

Enrolment: Apr17 – Oct18
Follow-up closed Oct19

	Cohort (2018)	Enrolled	% of cohort
Zagreb	1196	309	25.8%
Brighton	2338	565	24.2%
Barcelona	5496	549	10.0%
Antwerp	2976	249	8.4%
Lisbon	1220	579	47.4%

Uptake varied at sites: overall ~23% of each cohort enrolled in EmERGE

Clinician engagement
- *Change to practice*
- *Lack of virtual tariff*
- *Perceptions of digitalising clinical work*

Patient choice
- *Change to current pathway*
- *No smart phone*
- *Confidentiality*

Technical aspects
Research questionnaires

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3.6 % had withdrawn from the study by 12 months; with a further 3.8% by 30 months

Withdrawals from study pathway:

0-6 months	32
6-12 months	50
12-18 months	61
18-24 months	11
24-30 months	12

> 82/2251 by 12 months = 3.6%
> 166/2251 by 30 months = 7.4%

Reasons recorded:

- Participant choice [57]
- Moving away [45]
- Investigator decision [40]
- Pregnancy [3]
- Death [5]
- Viral load failure [3]
- Other [13]

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Demographics of those enrolled in the study represented those of the clinic cohorts.

EmERGE cohort: demographics (n=2251)	
Median age (range)	43.7 years (20-84 years)
Median baseline CD4 (IQR)	732 cells/mm^3 (553-949)
Male	2041 (91.0%)
Female	202 (9.0%)
Trans	1
Age over 50	630 (28.1%)
Non-national at site	460 (20.5%)
People who inject drugs	83 (3.7%)

- 70-84% full time employment: median 37.5 hours / week monthly income $1580
- 5-16% social service support median $318-1558/month

The oldest participant was 84.

Additional interviews & focus groups held with women & PWUD in the third stage of the co-design process.

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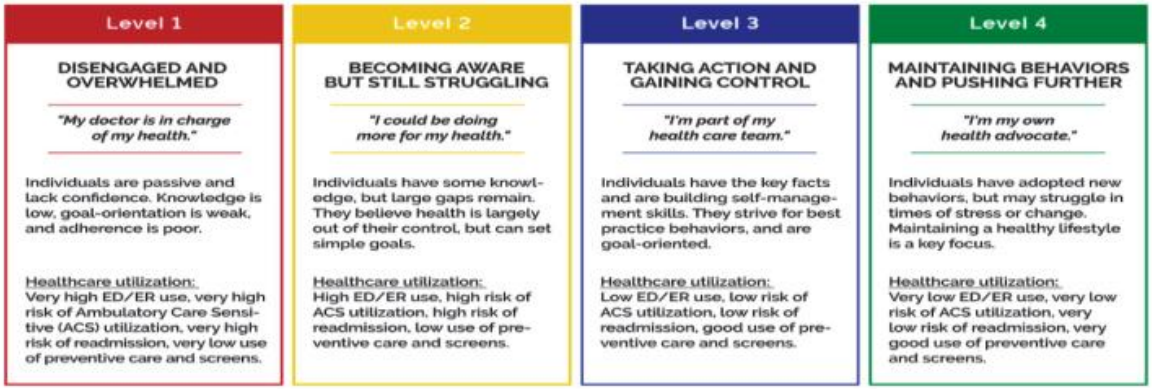
Primary outcome: empowerment – PAM-13

Score: 0-100

A change of 4 points on the PAM-13 scale is considered to be a minimal clinically important difference.

PAM-13 can be expressed as a continuous score (0-100) or can be interpreted as four levels of activation



Levels 1-4: A change of 1 level is considered clinically important.

Hibbard et al., 2004; Hibbard et al., 2005

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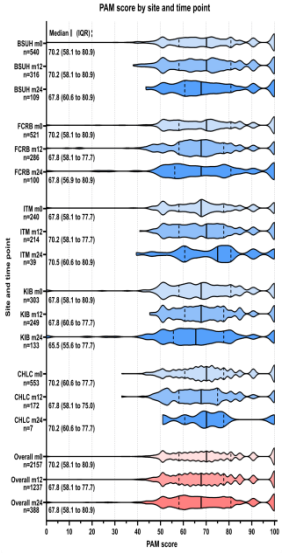
Across all sites individuals' PAM-13 scores showed high levels of activation

Overall questionnaire completeness:
Baseline 95.8%; 12 months 55.0% (range by site 29.6-87.7%)



Median PAM-13 scores at baseline:
70.2 (IQR 58.1 to 80.9)

Level 1	Level 2	Level 3	Level 4
DISENGAGED AND OVERWHELMED	BECOMING AWARE BUT STILL STRUGGLING	TAKING ACTION AND GAINING CONTROL	MAINTAINING BEHAVIORS AND PUSHING FURTHER
"My doctor is in charge of my health."	*"I could be doing more for my health."*	*"I'm part of my health care team."*	*"I'm my own health advocate."*
Individuals are passive and lack confidence. Knowledge is low, goal-orientation is weak, and adherence is poor.	Individuals have some knowledge, but large gaps remain. They believe health is largely out of their control, but can set simple goals.	Individuals have the key facts and are building self-management skills. They strive for best practice behaviors, and are goal-oriented.	Individuals have adopted new behaviors, but may struggle in times of stress or change. Maintaining a healthy lifestyle is a key focus.
4.1%	12.7%	45.7%	37.5%

The most common level was '3'
(individuals appear to be taking action but may lack the confidence & skill to support their behaviours)

followed by '4'
(individuals have adopted many of the behaviours needed to support their health).

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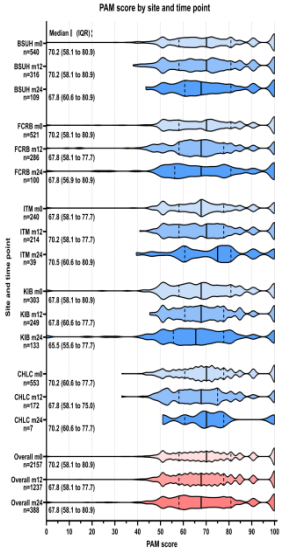
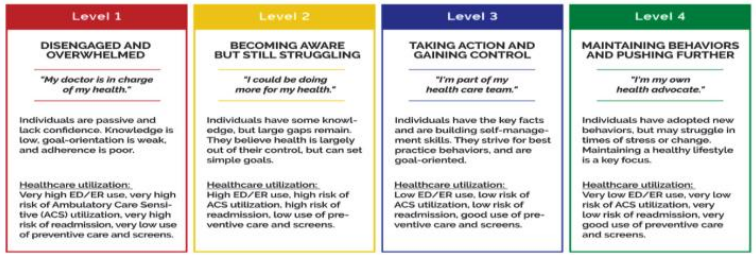
There was no evidence of a clinically important difference in overall score or level between M12 and M0 or M24 and M0

A mixed effects linear regression model was fitted for 2196 participants for a total of 3781 observations.



PAM continuous score:
Average overall change in continuous score from M12 to M0 was
- 0.95 (99% CI -2.10 to 0.19, p=0.031)
Average overall change in continuous score from M24 to M0 was
- 1.19 (99% CI -3.32 to 0.93 (p=0.148)



PAM Levels:
M12 compared to M0:
OR=0.89 (99% CI 0.73 to 1.10, p=0.164)
M24 compared to M0
OR = 0.91 (99% CI 0.65 to 1.27, p=0.446)

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Health economics analysis

Managing capacity: mean per patient year outpatient visits

- 4 sites: 9-31% ↓ associated costs: 9-33%
- 1 site: 8% ↑
  (closure of one clinic > extra visits)

- Cost of ARVs comprised 83-91% annual outpatient costs
- Primary outcome measures did not change substantially

- ARVs were the main drivers of cost
- Other structural changes to clinics affect costs
- Importance in managing capacity (e.g. during COVID-19)

Correspondence to: Dr EJ Beck, NPMS-HHC CIC, 21 Bedford Square, London, WC1B 3HH, UK, ejbeckphase2017@gmail.com

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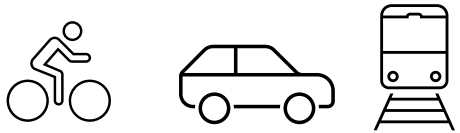

- 28-50% of participants took time off work to attend clinic
- Return trip to clinic median 1.5-2.0h; median cost $5-$41

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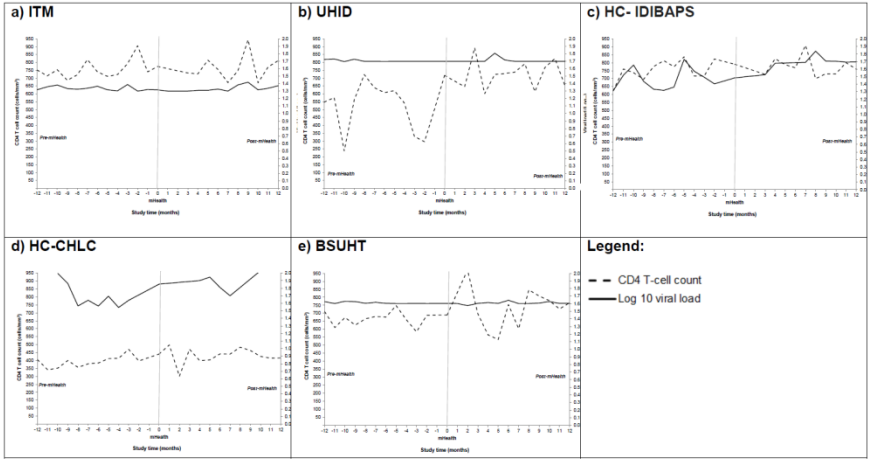
HIV Viral load outcomes remained excellent



Beck, submitted for publication

10 individuals with VL >50 copies/ml x2; none lost to follow up

Self reported adherence - M-MASRI VAS:

- *Baseline 100% (IQR 98%-100%)*
- *12 months 100% (IQR 97%-100%)*
- *24 months 100% (IQR 98%-100%)*

No (0/65) Serious Adverse Events related to the pathway or platform were reported during 3891 patient years of follow-up

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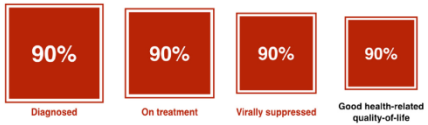
Health Related Quality of Life

EQ-5D-5L; PROQOL-HIV

‘the 4th 90’



- EQ-5D-5L:
  - in general good HRQOL reported in all domains across all sites & time points
  - Where problems are reported, pain and anxiety / depression were most common

- PROQOL-HIV:
  - Participants scored highly in all domains except Stigma
  - Some variations between sites in Stigma, Health Concerns & Treatment Impact domains
  - Ratings for general health were similar across sites & time points with > 81.9% participants in the good or very good categories at each time point

Lazarus et al. BMC Medicine (2016) 14:94

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Patient experience

94.6% would recommend EmERGE to a friend

	Would recommend	Service rated good/excellent	System usability score
Zagreb	97%	87%	91.3 (80.0-97.5)
Brighton	92%	85%	80.0 (65.0-92.5)
Barcelona	94%	77%	77.5 (62.5-90.0)
Antwerp	90%	77%	82.5 (67.5-90.0)
Lisbon	96%	84%	85.0 (70.0-95.0)

Usability rated as **85/100**
On System Usability Score
(score over 68 is considered above average)

83% rated the service as good or excellent;
14% as satisfactory;
3% poor.

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EACS guidelines 2019

- *If people have been stable on ART for 6 months or more, with no other significant issues,* ***clinicians could consider using alternative modalities such as email/phone/or other electronic means.***

- *This form of consultation can have the* ***same validity as a face-2-face consultation if properly instituted in a clinical protocol.***

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Summary points

- Role for digital health pathways in person-centred care for people living with HIV

- Feasible & acceptable *option* in the menu of care; 23% of clinic cohorts enrolled
- Secure, trusted, co-designed pathway & platform; providing access to own data

- Virological outcomes remain excellent; patient activation high in this population
- HRQOL measures generally scored highly; still some key areas – including stigma

- Helps clinics to manage outpatient capacity – reducing face-to-face outpatient visits (up to 30%) for people living with medically stable HIV

- Usability & patient experience good; importance of co-design & sustainability

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EmERGE

The EmERGE Consortium

Acknowledgements

Community groups and participants at each site:

- Zagreb
- Antwerp
- Barcelona
- Lisbon
- Brighton

Martin Fisher
1964 - 2015

www.emergeproject.eu

EmERGE Advisory board: Richard Harding; Cesar Caceres; Agathe Leon; Alec Miners, Ed Wallitt

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