Fast-Track Cities Implementation Science Fund
LOI DEVELOPMENT WEBINAR

FAST-TRACK CITIES

IAPAC INTERNATIONAL ASSOCIATION OF PROVIDERS OF AIDS CARE

June 19, 2020

Objectives

- Introduce the *Fast-Track Cities Implementation Science Fund*
- Define implementation science
- Describe implementation science frameworks and methodologies within the context for this grant
- Discuss the relevance of implementation science in clinical and community settings within the context of this grant
- Review letter of intent (LOI) requirements and submission process
- Address queries from prospective applicants

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About the Fast-Track Cities Initiative

- **July 2014** – City initiative discussed by UNAIDS, IAPAC & Mayors at AIDS 2014
- **August 2014** – Partnership between UNAIDS, IAPAC, UN-Habitat & Paris
- **December 2014** – Fast-Track Cities launched World AIDS Day 2014 in Paris
  - 26 cities signed *Paris Declaration on Fast-Track Cities* on December 1, 2014
  - 300+ cities have joined the Fast-Track Cities network as of June, 2020

Full list of Fast-Track Cities: https://www.iapac.org/fast-track-cities/about-fast-track/

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RIGHT PLACE, RIGHT THING

RIGHT PLACE

- 200 cities account for ~60% of PLHIV
- 1 city may account for ≥40% of PLHIV
- Signing enough cities in a country to have impact on national HIV epidemic (e.g., Brazil, South Africa, UK, USA, etc.)
- "Laboratories of innovation"
- Local accountability for response
- Targeted responses using geolocated data

RIGHT THING

- Prioritize 90-90-90 on trajectory to GTZ
- Leverage political will/action
- Address health inequalities
- Reach key & vulnerable populations
- Close care & prevention continua gaps
  - Stigma/discrimination
  - Testing/link to care/treatment/suppression
  - PrEP as adjunct to treatment as prevention
  - Quality of life & quality of care

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Fast-Track Cities Implementation Science Fund

IAPAC has created and will manage the Fast-Track Cities Implementation Science Fund that will award up to 10 research grants in 2020 to clinician and community researchers in Fast-Track Cities.

Fast-Track Cities Implementation Science Fund Expert Review Committee		
Name	**City/Country**	**Affiliation**
Ms. Solange Baptiste	Johannesburg, SOUTH AFRICA	International Treatment Preparedness Coalition
Dr. Stefan Baral	Baltimore, MD, USA	Johns Hopkins University
Dr. Maggie Czarnogorski	Washington, DC, USA	ViiV Healthcare
Dr. Chris Duncombe	Washington, DC, USA	International Asspciation of Providers of AIDS Care
Dr. Elvin Geng	St. Louis, MO, USA	Washington University of St. Louis
Dr. Peter Godfrey-Faussett	Geneva, SWITZERLAND	Joint United Nations Programme on HIV/AIDS
Dr. James Hargreaves	London, UNITED KINGDOM	London School of Hygiene and Tropical Medicine
Dr. Dennis Israelski	Foster City, CA, USA	Gilead Sciences
Mr. David Michels	Paris, FRANCE	AIDES
Dr. Saiqa Mullick	Johannesburg, SOUTH AFRICA	University of the Witwatersrand
Dr. Thomas Odeny	Nairobi, KENYA	Kenya Medical Research Institute
Dr. Izukanji Sikazwe	Lusaka, ZAMBIA	Centre for Infectious Diseases in Zambia

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Fast-Track Cities Implementation Science Fund
Defining Implementation Science

For purposes of this grant, IAPAC defines “implementation science” based on a systematic review commissioned by the World Health Organization (WHO):

“Implementation science is a multidisciplinary specialty that seeks generalizable knowledge about the behavior of stakeholders, organizations, communities, and individuals to understand the scale of, reasons for, and strategies to close the gap between evidence and routine practice for health in real-world contexts.”

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JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Framing of HIV-Related Implementation Research

IAPAC FTC June 19, 2020

Stefan Baral, MD MPH FRCPC CCFP
Department of Epidemiology
Johns Hopkins School of Public Health

Overview

- Implementation Research In Practical Terms
- Conceptual Frameworks
- Implementation Outcomes and Strategies

Ideas as to why you are here

- Promising research, disappointing application
- Challenges with bringing interventions to scale
- Need to understand the “why” and “how” behind intervention success and failure
- Desire to increase the impact of interventions
- Growing recognition of the role and value of research-practice partnerships

Current Status of the Field in HIV

- A bit chaotic
- Many organizations and individuals with different approaches to implementation research and practice
- A prediction on the future of implementation research and practice
- Implications for this training

Definitions

- Implementation
  - The use of strategies to introduce or change evidence-based health interventions (policies, programs, individual practices) within specific settings

- Implementation Science in HIV
  - Implementation science is a multi-disciplinary field that seeks generalizable knowledge about the behaviour of stakeholders, organizations, communities, and individuals in order to understand the magnitude, reasons for and strategies to close the gap between evidence and routine practice for health in real world contexts

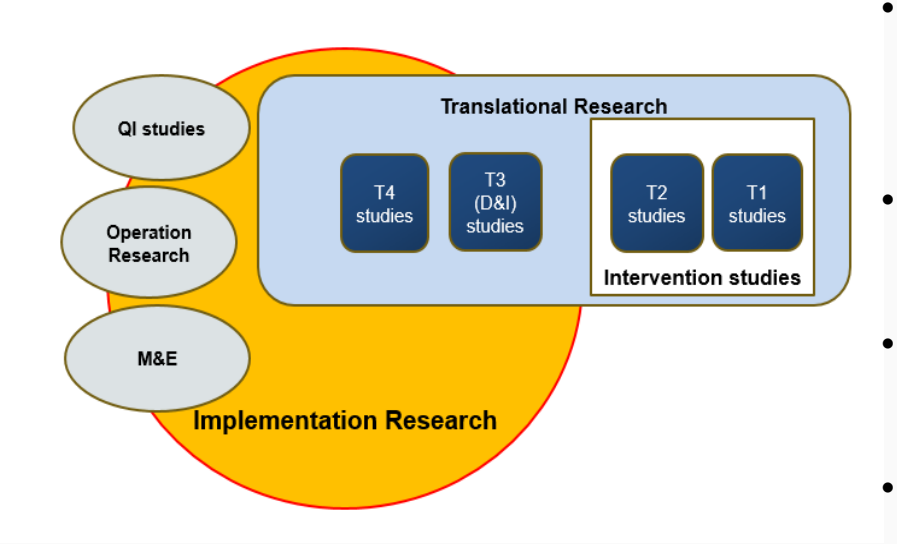
  - Key Themes
    - Multidisciplinary
    - Generalizable
    - Multiple stakeholders
    - Closing gap between evidence and practice
    - Real world contexts

Lobb and Coldtiz, Implementation Science and Its Application to Population Health Annual Review of Public Health, 2013; Odeny, Padian, Doherty, Baral, Beyrer, Ford, Geng, Definitions of implementation science used in the HIV/AIDS literature: a synthetic review. The Lancet Infectious Diseases, In Press, 2015

Implementation Research In Practical Terms

- Implementation science and practice in health focuses on:
  - identifying common implementation problems
  - understanding the factors that hinder or facilitate access to health interventions
  - developing and testing solutions to tackle implementation barriers
  - determining the best way
    - to introduce potential solutions into a health system
    - learning how to promote its large-scale use and sustainability

Implementation Research and Other PH Study Designs



- T1 involves processes that bring ideas from basic research through early testing in humans
- T2 involves the establishment of efficacy in humans
- T3 primarily focuses on implementation and dissemination research
- T4 focuses on outcomes and effectiveness in populations

Source: Olakunle Alonge, Lobb and Coldtiz, Implementation Science and Its Application to Population Health Annual Review of Public Health, 2013; https://catalyst.harvard.edu/pathfinder/t2detail.html

Characteristics of Implementation Research

- Findings are Warranted to Inform Policy/Program
  - There is “sufficient evidence” to support the conclusions of the work
    - What is sufficient evidence?

- Transparency of Methods
  - Support Critical Assessment of the Study
    - Whether processes are adequate
    - Conclusions justified
    - Repeatability
  - Don’t be afraid of “failure”
    - A well done study is still a success in terms of generating generalizable knowledge

Differences with IR

Competencies on a IR team:

- Research Methodologist
  - Qual, Quant, Mixed Methods
- Ministry, Government, Agencies
  - Either as members of team or study oversight committee
- Health Professionals
  - Involvement of health professionals from study settings
- Communications
- Public Health Professionals
  - Health Commissioner/Associate Health Commissioner
  - Public Health Inspector/Public Health Nurse
- Privacy Expert
- Stakeholder Assessment
  - Community

http://www.who.int/tdr/publications/year/2014/ir-toolkit-manual/en/

Conceptual Frameworks Commonly used in IR

- RE-AIM
  - Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance

- Stages of implementation
  - National Implementation Research Network
  - Exploration and Adoption, Program Installation (Prep), Initial Implementation (pilot/adapt), Full Implementation (>50% coverage), Sustainability

- Consolidated Framework for Implementation Research
  - Intervention Characteristics, Inner Setting, Outer setting, Individuals in the Intervention, Implementation process
- Many others….

Source: Glasgow et al 1999, *National Implementation Research Network, 2005, Damschroder, 2009*

Lots of frameworks

- CFIR
- Diffusion of innovation
- Blueprint for Dissemination
- OPTIONS Model
- Knowledge Exchange Framework
- Push-Pull Capacity Model
- 4E Framework for Knowledge Disseminations and Utilization
- PRECEED
- RE-AIM
- PRECEDE-PROCEED
- DHAP
- PRISM
- Active Implementation Framework
- Normalization Process Theory
- PHARIHS
- PRISM
- 4Es
- ARC
- Etc. etc.

[Tabak et al. Am J Prev Med 2012]

Frameworks

- Frameworks provide descriptive categories but do not generally provide explanations, predictions, or descriptions of relationships between categories

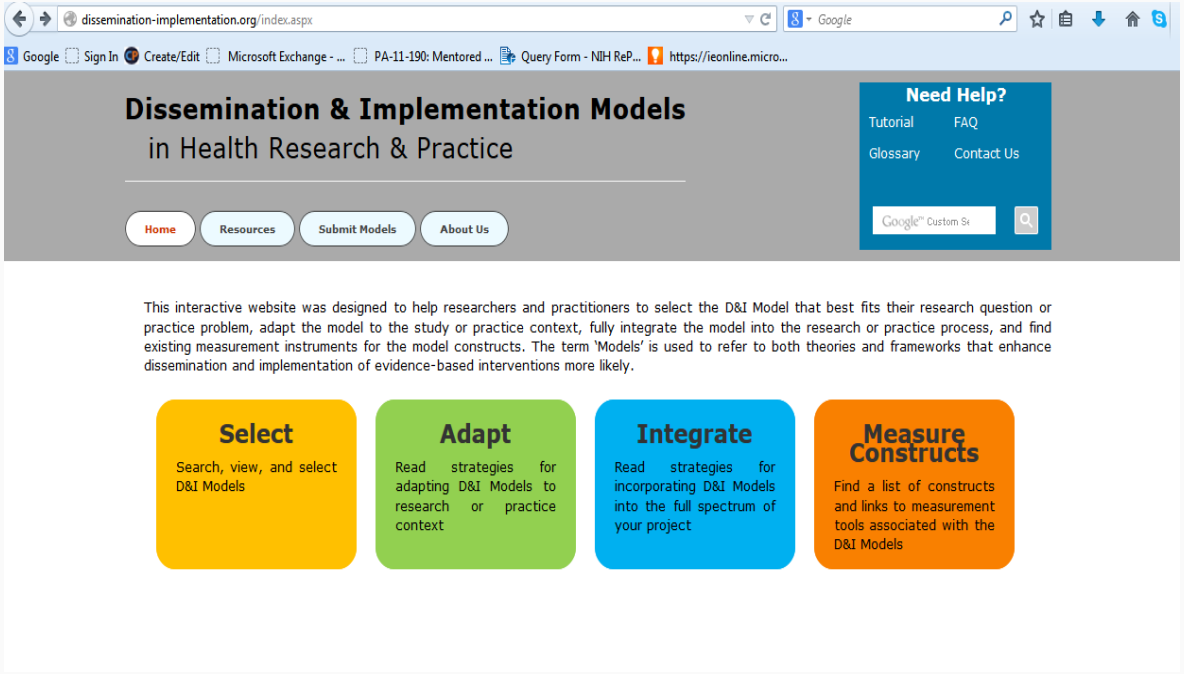
- Implementation Planning and Process frameworks (models)
  - EPIS, K2A, RE-AIM
    - Steps along implementation pathway

- Implementation Determinants Frameworks
  - PARIHS, CFIR
    - Specify domains that have been recognized as important for implementation

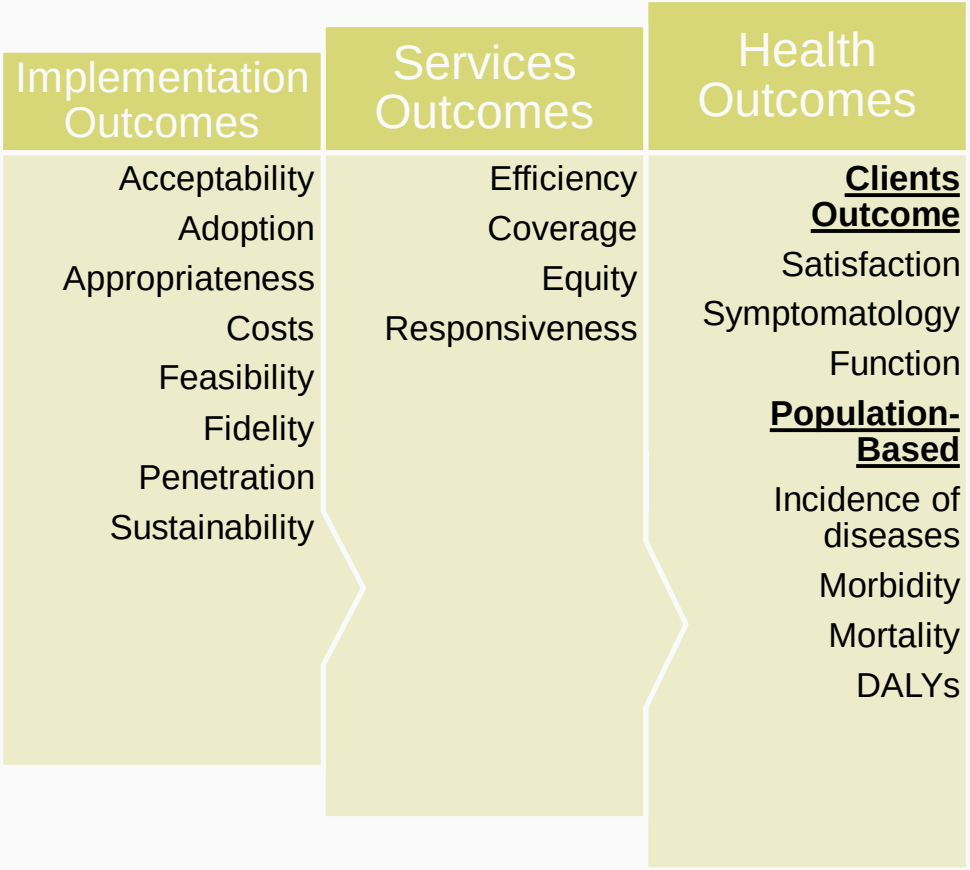
- Implementation Evaluation Frameworks
    - RE-AIM; Proctor
      - List of key implementation outcomes

Need support selecting a model?

- dissemination-implementation.org



Outcomes in Implementation Research



Source: Olakunle Alonge, *Proctor et al 2011*

Implementation Outcomes

- Are they doing the programs as intended? (*implementation outcome)*
- Yes, they are and it is/isn't resulting in good outcome (*effectiveness outcome*)
- Only when EBI are fully implemented should we expect positive outcomes *(IOM 2001)*
- Implementation outcomes are:
  - Results of implementation process
  - Can be used to evaluate the success of implementation
  - Proximal indicators of implementation process
  - Key intermediate outcomes to effectiveness outcomes
  - Underdeveloped constructs; operates across socio-ecological levels

Implementation Outcomes

Implementation Outcome	Working Definition*	Related terms**
Acceptability	Perception among stakeholders that an intervention is agreeable	Related factors: (e.g. Comfort, Relative advantage, Credibility)
Adoption	Intention, initial decision, or action to try to employ a new intervention	Uptake, Utilization, Intention to try,
Appropriateness	Perceived fit or relevance of the intervention in a particular setting or for a particular target audience (e.g. provider or consumer) or issue	Relevance, Perceived fit, Compatibility, Perceived usefulness or suitability
Feasibility	The extent to which an intervention can be carried out in a particular setting or organization	Practicality, Actual fit, Utility, Trialability
Fidelity	The degree to which an intervention was implemented as it was designed in an original protocol, plan, or policy	Adherence, Delivery as intended, Integrity, Quality of programme delivery, Intensity or dosage of delivery
Implementation cost	Incremental cost of the implementation strategy	Marginal cost, Total cost***
Coverage	Degree to which the population that is eligible to benefit from an intervention actually receives it.	Reach, Access, Service Spread or Effective Coverage, Penetration
Sustainability	The extent to which an intervention is maintained or institutionalized in a given setting.	Maintenance, Continuation, Routinization Institutionalization, Incorporation

Source: Proctor et al 2011; Peters, Adams, Alonge et al 2013

Fidelity Definition and Domains

- Definitions
  - Degree to which an intervention was implemented as prescribed by the original protocol or program developers
  - Balancing fidelity and adaptation: adherence to the core program components

Carroll et al. 2007	Proctor et al. 2011	Durlak and DuPre 2008
Adherence	Adherence	Adherence
Exposure or dose	Dose	
Quality of delivery	Quality of delivery	
Participant responsive ness		
Program differentiation		
Intervention complexity		
Facilitation strategies		

Adaptation

- *Adaptation*
  - *Purposeful changes to an intervention (with preservation of the core components) to:*
    - *Accommodate differences in contexts (inner and outer)*
    - *Improve fit to a target population*
- *Levels of adaptation*
  - *Contextual modifications*
    - *Settings and intervention recipients*
  - *Content modifications*
    - *Content of the interventions and implementation strategies*
  - *Training and evaluation modifications*
    - *Training and how outcomes [implementation and effectiveness] are evaluated*
- *Measurement*
  - *Documentation of processes*
  - *Before and after observation/survey of outcomes*
  - *Ratings*
  - *Qualitative approach*

Source: Stirman et al 2013

Implementation Strategies

- "Implementation intervention" as a method to "enhance the adoption of a 'clinical' intervention" (Curran et al 2012)
- Strategies to improve the process of care (Grimshaw 2006)
- Efforts and approaches that are designed to support or otherwise enhance an intervention (Peters, Adams, Alonge et al 2013)

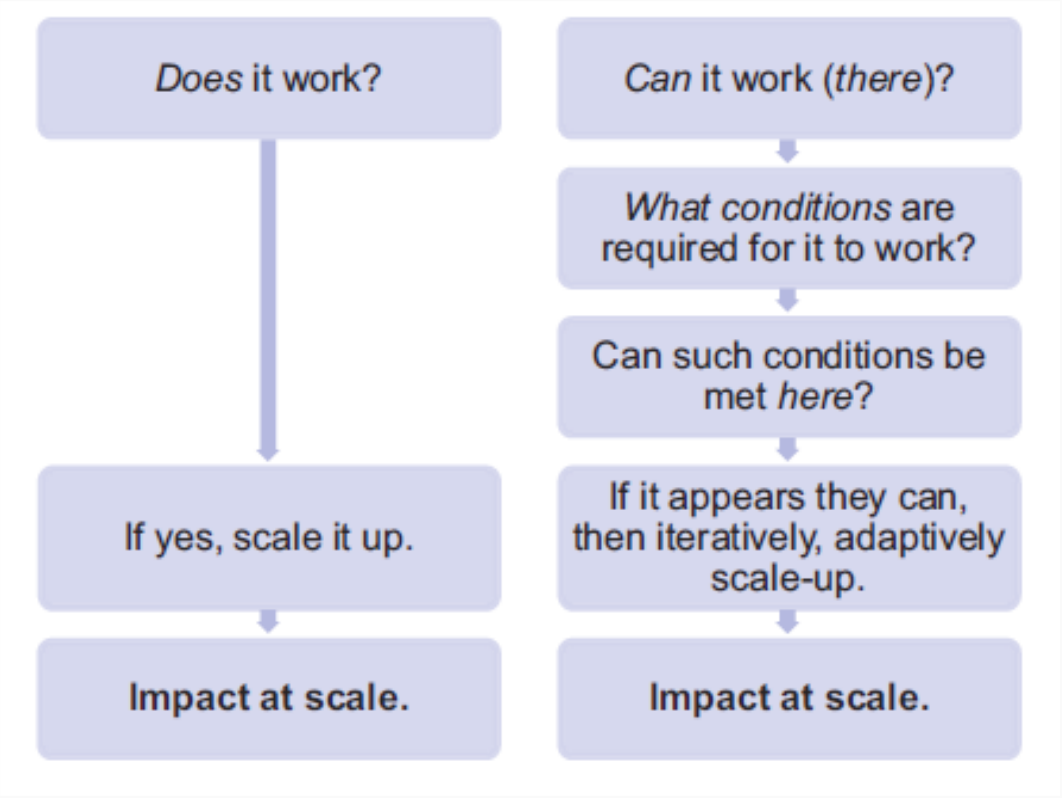
Implementation Strategies for Health Programs

Strategy Area	Implementation Strategy Examples
Individual Provider Improvement	***Continuing education and training;*** regulation , accreditation and licensing Peer learning; job aids; guidelines and standards; supervision and audit feedback
Household and Community Empowerment	***Community information and education:*** community health workers; training of community members such as youth, mothers ***Strengthen inclusion and participation:*** community managed services; community partnerships and co-management; community owned services ***Strengthen local accountability:*** joint monitoring; provider accountability schemes; community based information systems ***Local organizational capacity building:*** community mobilization; community boards and structures to oversee and manage ***Financial empowerment:*** community financing; community participatory budgeting
Provider Organizational Improvement	***Quality improvement/assurance:*** team problem solving; standard operating procedures Human resource management systems; logistics systems strengthening Strengthen financial management
Public Oversight	Corruption reduction strategies; enforcement approaches ; policy reviews Contracting; reorganize and/or integrate services ***Decentralize public service provision*** (deconcentration, delegation, devolution)
Multiple Agents	Assess needs and constraints: ***constraints reduction plans*** Obtain broad-based support of stakeholders: ***engage powerful interest groups***; coordinate with community organizations Flexible management processes and ***modification through stakeholder feedback***

Experimental Studies

- Explanatory (Traditional Gold Standard)
  - Understand and explain benefit of an intervention under controlled conditions
  - EI Type 1, Type 2, Type 3 Designs
  - Maximize internal validity
- Pragmatic Trials
  - Focus on the intervention in routine practice
  - Intentional maximization of variability in how study is implemented
    - Variability of research settings (communities, practice settings, types of providers, patients)
  - Maximize external validity
- Adaptive Designs
  - Emerging area of study that attempt to balance internal and external validity

Efficacy vs IR Evidence Paradigm



Source: Global Health Editorial. Women's Groups to Improve Maternal and Child Health Outcomes: Different Evidence Paradigms Toward Impact at Scale. 2015

What is community-based research ?

Definition:

- Community-based research is research that responds to the same methodological requirements as any other scientific research approach;
- Its specificity is on the **balanced** partnership between researchers and community actors. The idea is that we do research TOGETHER, guided by the **needs** and **knowledge** of those concerned;
- It is based on the principle of “doing with” and not “doing for”.

  Above all, the goal is social transformation

Community-based research and implementation science:

- Community-based research is not necessarily the synonym of program evaluation, interventional research or implementation research;
- Biomedical trials can be done with a community-based approach and community-based organizations can be involved in observational survey on key populations;
- BUT, in many cases and projects, questions about implementation of services, disseminations of new interventions, access to services are central in community-based research;
- The fact is that, very often, we do implementation science and research without knowing we do it;
- It means that, without any doubt, community-based organizations do have a lot of things to submit at this call of proposals.

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Example 1 : The ANRS – Qualipep study

Leverages and barriers to access to pre-exposition prophylaxis

Community and scientific findings in 2013:

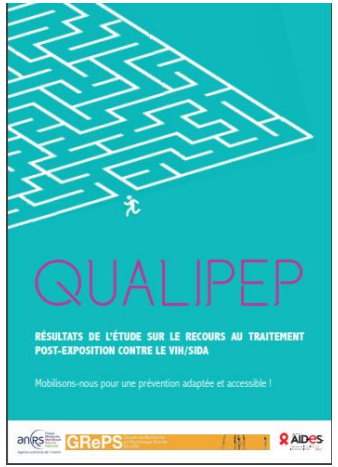
- No current national data on the number of people using PEP, their practices and profiles.
- PEP is little known tool, there is always a lack of information
- Missed opportunities, difficulties of access observed

Hypothesis:

- A better understanding of the barriers and leverages of access to and use of PEP would make it possible to offer a more suitable offer for people most exposed to HIV

Main objectives of the project:

- Characterize the use of PEP among the groups most exposed to HIV
- Interview the experience of prescribing PEP with healthcare staff from different services (sexual clinic, testing services, etc.)
- Assess the acceptability of a community PEP offer



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Example 1 : The ANRS – Qualipep study

Leverages and barriers to access to pre-exposition prophylaxis

Methodology:

- Qualitative methodology in a specific geographic area (Alpes Region)
- Three different groups of people were interviewed (semi-structured interviews): 11 people had followed a PEP in the past year, 9 people who took a risk and would have needed a PEP without benefiting from it, 9 prescribing doctors.

After analysis, the research conducts to improvement proposals for access to PEP:

- Information for the most exposed public
- Improve training of emergency doctors and harmonization of protocols
- Improve training in screening centers
- Advocate to change guidelines to have better tolerated treatments and review their duration
- Experiment community PEP offer

Some of these proposals have been retained and applied, but we are still waiting for community PEP !

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Example 2 : The ANRS – HERMETIC Project

Experiment a new testing strategy to reach individuals from Sub-Saharan

The Project:

- HERMETIC was a European project which aimed to link mathematical modelling and experimentations of new interventions.
- Mathematical modelling of the epidemic in France identified the “hidden epidemic” in France: a large part of people who don’t know their status are migrant men (heterosexuals and MSM) from sub-Saharan Africa living outside Paris.
- In AIDES, the question for the experimentation was : How can we improve our capacity to reach individuals from sub-Saharan Africa?
- Literature review, brainstorming and discussions led the decision to experiment a new approach to HIV testing: door-to-door.

Implementation questions were:

- Is door-to-door testing more efficient to reach Sub-Saharan individuals for screening ?
- Is this new intervention acceptable by people and by field workers ?
- Is this new intervention feasible ?

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Example 2 : The ANRS – HERMETIC Project

Experiment a new testing strategy to reach individuals from Sub-Saharan

To respond at theses questions we used a mixt method, qualitative and quantitative:

- We performed a analysis which compared testing data of a classical intervention with testing data of the new intervention
- We passed a questionnaire about acceptability with the proposition of testing
- We made interviews with fields workers

Results :

- 739 door-to-door contacts: 290 with people born in SSA (143 men et 147 women)= 39,2%
- 142 rapid tests with SSA-born people at the van and 43 at home.
- More native Sub-Saharan African people were reached than in classical interventions.
- The door-to-door testing offer in disadvantaged neighborhoods seems feasible and acceptable for

fields workers. Points of vigilance and adaptations have been identified to consider the desired renewal of this innovative experience.

At the moment, we don’t have yet implement this new testing strategy in AIDES, but it was a very useful experimentation to modify some points in our interventions guidelines !

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Q&A – 30 min

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Grant Overview

- Grant funding
  - Up to $50,000 + 10% capped indirect
  - 90% of funds must be spent in country where research is taking place
- Duration: 1 year (excludes time needed for ethics approval)
- Applicant eligibility
  - Community and Clinician researchers based in a Fast-Track City
    - Applicants with multiple affiliations must have at least one affiliation with a community based organization and/or clinical facility
    - Applicants who have both clinical and community affiliations must specify which applicant category they are submitting under
  - Primary applicants may include three sub-recipients from non-profit or for-profit organizations, community- and faith-based organizations, government and non-governmental organizations, and other institutions that can successfully execute the scope of work under the terms of the agreed research grant proposal.

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Grant Overview – Research Domains

Proposed studies should identify and address implementation gaps in existing, evidence based interventions/policies/programs across the HIV care and/or prevention continua.

- Finding and testing people who are living with HIV and unaware of their status
- Linkage to HIV prevention, care, and support services
- Prompt initiation of and adherence to antiretroviral therapy
- Retention and long-term engagement in HIV care, including maintaining viral suppression
- Switching to second- and third-line antiretroviral regimens
- Improving health-related quality of life and quality of care
- Sustaining HIV services during the COVID-19 pandemic
- Disparities in access to/utilization of HIV prevention and care services
- Optimized care for unique populations (children, adolescents, and aging people living with HIV)
- Intersecting stigmas, interventions, and the relationship with health care utilization
- Accelerated uptake of policies/diagnostics/medicines
- Optimizing multi-sectoral implementation strategies for HIV prevention
- Strategies to overcome gaps to rapid start and adherence to antiretroviral therapy
- Demand generation among key and hard to reach populations
- Integrated approaches to address co-morbidities including communicable and non-communicable diseases
- Accelerated update of policies/diagnostics/medicines or small scale testing of innovative health solutions

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LOI Development and Submission

The LOI should be on official letterhead, 3-5 pages in length, written in English, single-spaced, with a minimum font size of 11, Times New Roman font.

Sections:

- Introduction and Background
- Objective and Relevance
- Implementation Framework and Methodology
- Data Evaluation and Analysis Plan
- Intended Outcomes
- Proposed Timelines

Submission Materials:

- LOI on official letter head
- LOI supplemental information
  - Applicant Information
  - Illustrative Budget
  - Key Personnel Statement

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LOI Review and Next Steps

- The FTC Implementation Science Fund Expert Review Committee will review LOI submissions against a standardized rubric
- Select applicants will be invited to submit a full proposal and will take part in a proposal development workshop
- Full proposals will be reviewed by the Expert Review Committee and up to 10 (5 community and 5 clinician) grants will be awarded

IAPAC Fast-Track Cities Implementation Science Fund – LOI Scoring Rubric FAST-TRACK CITIES

Significance	Does the proposed implementation science research identify an existing implementation gap relevant to an existing evidence-based intervention, policy, or program? Is the proposed implementation science research likely to have long term impacts on policy and practice in the communities/countries in which the implementation science research is conducted?	1 2 3 4 5
Approach	Are the research questions to be answered, the implementation framework, design, methods, and analyses innovative, adequately developed, robust, and appropriate to the aims of the proposal? Does the application acknowledge potential problem areas and consider alternative tactics? Are the proposed timeline and milestones appropriate, feasible (especially in the era of COVID-19), and technically sound? Has the proposal involved local stakeholders and civil society in the choice of research questions and the design of the research study, and does it take local context into account to ensure relevance? Does the proposal include plans for reporting and dissemination of results?	1 2 3 4 5
Value	Is the cost appropriate for the complexity of the proposed work and the degree of risk and innovation proposed? Does the proposed project efficiently use resources?	1 2 3 4 5
Organizational/Investigator Capability	Is the research team appropriately trained, experienced, and positioned to carry out this work? Is there strong evidence of substantive organizational capability and commitment? Does the environment in which the work will be done contribute to the probability of success? Do the proposed interventions take advantage of unique features of local environment including partnerships and collaborative arrangements?	1 2 3 4 5
Sustainability	Does the proposed research address the applicability, replicability, scalability, effectiveness and cost-effectiveness of interventions with the goal of the translation and integration of research findings related to evidence-based interventions? What partnerships and parameters are in place to ensure impacts from the research proposal are sustainable beyond the duration of the project? How adaptable/scalable is the project within the existing health system and current policies?	1 2 3 4 5

1- Strongly Disagree 2- Disagree 3- Neither agree nor disagree 4- Agree 5- Strongly Agree

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Q&A – 30 MIN

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Thank you

- Fast-Track Cities Implementation Science Expert Review Committee
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  - Mr. David Michels
  - Dr. Saiqa Mullick
  - Dr. Thomas Odeny
  - Dr. Izukanji Sikazwe
- Dr. José M. Zuniga, CEO and President of IAPAC
- Our donors, ViiV Healthcare and Gilead Sciences
- Our colleagues at UNAIDS, for their continued partnership on the FTC initiative

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