An update on PrEP in Europe

Speakers: Dr Valentina Cambiano of University College London, Daniela Rojas Castro of AIDES and Dr Anastasia Pharris of the European Centre for Disease Prevention and Control (ECDC).

Chaired by Gus Cairns of EATG
PrEP background

Gus Cairns
Editor, NAM / www.aidsmap.com
Prevention coordinator, EATG
Co-chair, PROUD Study
HIV is on the increase in at least one group


Health Protection Agency. 

Caein F et al. 
And more so elsewhere...

HIV MSM diagnoses: Poland 2000-11, east Asia 2002-2007

Ergo: Pre-exposure prophylaxis

• Idea of medicines to prevent conditions not new:
  o Antimalarial prophylaxis (‘tonic water’)
  o Isoniazid prophylaxis for TB
  o Co-trimoxazole for PJP (PCP)
  o Statins for heart attacks

• And of course:
  o The contraceptive pill
PrEP history

- First animal study: 1995\textsuperscript{1}
- First study in infants: 2003\textsuperscript{2}
- First adult study (terminated): Cambodia, 2004\textsuperscript{3}
- First result (65\% reduction in infections, but not significant): Ghana, 2006\textsuperscript{4}
- First significant result (44\% effectiveness): iPrEx, 2010\textsuperscript{5}

5. Grant RM et al. Preexposure chemoprophylaxis for HIV prevention in men who have
PROUD Pilot

GMSM reporting UAI last/next 90 days; 18+; and willing to take a pill every day

Randomize HIV negative MSM (exclude if treatment for HBV/Truvada contra-indicated)

Risk reduction includes Truvada **NOW**
Risk reduction includes Truvada **AFTER 12M**

Follow **3 monthly** for up to 24 months

Main endpoints in Pilot: recruitment and retention
From April 2014: HIV infection in first 12 months
Follow 3 monthly for up to 24 months
Individual incident HIV infections

Immediate PrEP

Deferred PrEP

N=3

N=1 9
Ipergay : Event-Driven iPrEP

- 2 tablets (TDF/FTC or placebo) 2-24 hours before sex
- 1 tablet (TDF/FTC or placebo) 24 hours later
- 1 tablet (TDF/FTC or placebo) 48 hours after first intake
Mean follow-up of 13 months: 16 subjects infected

14 in placebo arm (incidence: 6.6 per 100 PY), 2 in TDF/FTC arm (incidence: 0.94 per 100 PY)

KM Estimates of Time to HIV-1 Infection (mITT Population)

86% relative reduction in the incidence of HIV-1 (95% CI: 40-99, p=0.002)
Is PrEP for HIV prevention cost-effective in MSM?

Dr Valentina Cambiano
Summary

- What is a cost-effectiveness analysis?
- Why are we evaluating whether PrEP is cost-effective?
- How is cost-effectiveness determined?
- Is PrEP cost-effective among MSM in the UK?
Cost-effectiveness analysis (CEA)

- CEA is a form of economic evaluation that informs the choice of healthcare interventions/programmes
- Based upon comparative assessments of costs & health consequences
Why are we evaluating whether PrEP is cost-effective?

New interventions
- Health gained
- Additional Cost

Budget constrained health care systems

Interventions displaced or foregone
- Health forgone
- Resources released
Why are we evaluating whether PrEP is cost-effective?

Goal: maximize health of the population

New interventions
- Health gained
- Additional Cost

Interventions displaced or foregone
- Health forgone
- Resources released

Budget constrained health care systems

Is the new intervention cost-effective?

Is the health gain from the new intervention likely to be greater than the health forgone?
Steps 1-2 to determine cost-effectiveness

1. Determine the costs of alternative interventions

2. Measure and value health outcomes (HIV infections, life-years, Quality-adjusted life-years (QALYs))
Quality adjusted life-years (QALYs)

- QALYs measure health on a scale from 0 (representing death) to 1 (full health).

Extent of being healthy given by thickness of orange line

Person is dead

<table>
<thead>
<tr>
<th>Person</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>7 QALYs</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>5.5 QALYs</td>
<td>5.25</td>
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<td>5.5 QALYs</td>
<td>5.25</td>
<td>4.25 QALYs</td>
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</tbody>
</table>
Steps 3-4 to determine cost-effectiveness

3. **Compare** costs and health outcomes (to the reference scenario, usual care)

4. Calculate the ‘incremental cost-effectiveness ratio’ (ICER): the cost per QALY gained from an alternative.

\[
ICER = \frac{\text{Cost↓PrEP} - \text{Cost↓No PreP}}{\text{QALY↓PreP} - \text{QALY↓No PreP}}
\]
5. Compare the ICER to a **threshold ICER** (sometimes called the cost-effectiveness threshold or willingness to pay threshold)

- The threshold represents the **opportunity cost**, the value of the alternative that is foregone
- In the UK the threshold is around £20,000/QALY gained

**IF we adopt an intervention with ICER > £20,000/QALY gained**

--- more health lost/forgone from the commitment of resources to that intervention than results from its provision
Concept of cost-effectiveness threshold – ideal scenario

Width of bar indicates total cost of implementing the intervention in a country.
Is PrEP for HIV prevention cost-effective in MSM in the UK?

<table>
<thead>
<tr>
<th></th>
<th>Public Health England</th>
<th>UCL</th>
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<tbody>
<tr>
<td><strong>Type of model</strong></td>
<td>Static</td>
<td>Dynamic</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>PrEP for 1 year</td>
<td>PrEP when having CLS once initiated</td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>MSM presenting with bacterial STI</td>
<td>Different MSM groups</td>
</tr>
<tr>
<td><strong>Timeframe</strong></td>
<td>Life-time</td>
<td></td>
</tr>
<tr>
<td><strong>Eligibility criteria</strong></td>
<td>Eligibility criteria as in PROUD (CLS in the last 3 months and tested in the last year)</td>
<td></td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Considering cost obtained a from Freedom of information Act request (lower, possibly closer to reality)</td>
<td></td>
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</tbody>
</table>
PHE model

• PrEP in high risk MSM is unlikely to be cost-effective at 64% effectiveness plus risk compensation, given to a population with 3.3% Year 1 HIV incidence (ICER £34,000/QALY gained) → ICER becomes less favourable if target population’s Year 1 incidence is lower.

• Estimated cost-effectiveness of PrEP is very sensitive to:
  − target population’s Year 1 HIV incidence;
  − patient adherence (much uncertainty, especially with programme scale-up) → affects effectiveness;
  − PrEP drug cost

• **Conclusions:** Substantial price reductions of anti-retroviral drugs used for PrEP is needed to give necessary assurance of cost-effectiveness, & for an affordable public health programme of sufficient size.
Number (%) of MSM projected to be on PrEP

By 2096:
128,300 (20%) on PrEP

Men who tested for HIV and had
- CLS
- CLS with ≥1 STP
- CLS with ≥5 STP
- CLS with STIs
- CLS (no increase in CLS or testing)

90% range
Overall cost of ART and of PrEP

1 year on ART (CD4>200 cells/mm$^3$):

£6,488 Atripla (BNF 2015)
£4,063 Healthcare
£164 (£41x4) CD4 measurements
£276 (£69x4) VL measurements
[£238 resistance test at ART initiation]

~£11,000

1 year on PrEP:

£4,331 Truvada (BNF 2015)
£234 First visit for PrEP
£232 (£58x4) HIV tests
£284 Additional cost of monitoring people on PrEP compared to people at similar risk not on PrEP

~£5,000
Health benefits and costs over 80 years

PrEP in men having:
- CLS
- CLS with ≥1 STP
- CLS with ≥5 STP
- CLS with STIs
- CLS (no increase in CLS or testing)

Cost-effectiveness threshold range

*discounted at 3.5% rate

Additional cost (vs No PrEP)

Health benefit

<table>
<thead>
<tr>
<th>Health benefit</th>
<th>Additional cost (vs No PrEP)</th>
</tr>
</thead>
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<tr>
<td>£57,145</td>
<td>£0</td>
</tr>
<tr>
<td>£39,314</td>
<td>£9,466</td>
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<tr>
<td>£9,290</td>
<td>£1,522 m saved</td>
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<td>£9,290</td>
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Health benefits and costs over 80 years

PrEP in men having:
- CLS
- CLS with ≥1 STP
- CLS with ≥5 STP
- CLS with STIs
- CLS (no increase in CLS or testing)

Cost-effectiveness threshold range; 50% reduction in cost of ARVs
- £23,847
- £13,010
- £471 m saved
- £660 m saved
- £2,097 m saved

Cost-effectiveness threshold range; 80% reduction in cost of ARVs
- £3,934
- £299 m saved
- £1,169 m saved
- £1,623 m saved
- £2,426 m saved

*discounted at 3.5% rate
Preliminary Conclusions

This analysis suggests that the use of PrEP among MSM in the UK is cost-effective when:

- it is targeted to men who had 5 STPs or more in the last year without using condom or present with an STI

or

- the cost of ARVs is assumed at least 50% lower than current full list prices, once patents expire (which seems realistic based on past experience and may well be an under-estimate)

or

- when there is no increase in CLS and not an increase in HIV test, as a consequence of PrEP becoming available
Thank you very much to:

Andrew Phillips
Alec Miners
David Dunn
Sheena McCormack
Gus Cairns
Alison Rodger
Fumiyo Nakagawa
Catherine Mercer
Legion computing cluster (Legion@UCL)

PHE team
KohJun Ong
Sarika Desai
Monica Desai
Anthony Nardone
Albert Jan van Hoek
Noel Gill

...and you for your attention!
Is it cost-effective among MSM in other resource rich settings?

- high-risk MSM in New York ✓ (ICER $32,000). Desai et al 2008
- high-risk MSM in the US unlikely, unless price reductions and/or increases in efficacy. Possibly cost-effective in younger populations or populations at higher risk of infection (ICER $298,000). Paltiel et al 2009
- high-risk MSM in the US ✓ (ICER>$40,000), but annual PrEP expenditures of more than $4 billion. Juusola et al 2012
- MSM in a discordant regular partnership in Australia ✓ (ICER > $110,000), but not large population level impact, other scenarios unlikely. Schneider et al 2014
- MSM in Canada (using on demand PrEP) ranges from cost-saving to highly cost-effective. Ouellet 2015
Challenges to the implementation of PrEP in Europe

Anastasia Pharris
ECDC Programme on HIV, STI and viral hepatitis
Steps from evidence generation to clinical application

1. Evidence Generation
   - Research funding

2. Evidence synthesis

3. Policy formation

4. Policy application

Guidelines Development

Clinical decisions
- Patient circumstances
- Provider skills
- Evidence

Slide courtesy of Dawn K. Smith, CDC
Issues influencing policy formation and application

• Efficacy of the intervention
• Public and individual health rationale
HIV infections diagnosed among MSM in Europe have increased during the last decade.

Source: ECDC/WHO (2014). HIV/AIDS Surveillance in Europe, 2013. Data from Estonia and Poland excluded due to incomplete reporting on transmission mode during the period; cases from Italy and Spain excluded due to increasing national coverage over the period.
Issues influencing policy formation and application

• Efficacy of the intervention
• Public and individual health rationale
• Regulatory issues
• Guidelines (regional, national and local)
Diverse health systems in Europe which affect the organisation and delivery of health care

- National health systems
- Mixed health insurance
- Private insurance
- Out-of-pocket payment

How health care is organised and financed will affect decisions on the payment threshold for PrEP

In Europe, health provision tends to be state-provided and financed and the decision to provide PrEP is done by public bodies considering cost constraints.
PrEP as a medicine and a prevention method

NGOs and public health bodies

- HIV prevention often occurs via NGOs and public health authorities

Hospitals and clinical bodies

- HIV medicines procurement and provision for treatment has occurred via clinical bodies, hospitals

The provision of PrEP is a comprehensive package which necessitating collaboration and task-sharing
Where to target PrEP?

Risk group approach?
MSM, people who inject drugs, sex workers

Risk assessment approach?
Persons having condomless receptive anal intercourse
STI diagnosis or PEP use during last six months
Situations heralding ‘seasons of risk’

Self-referral approach?
Those who ask for PrEP

Groups to target are likely to differ depending on the national/sub-national epidemiological situation
One-third of new HIV diagnoses among MSM are among men <30 years

Source: Adapted from Pharris, Eurosurveillance (2014). Excludes data from countries with changed coverage over the period (Bulgaria, Italy, Spain) and incomplete data on transmission mode (Estonia, Poland)
Largest proportional increases in new HIV diagnoses among MSM are in countries in Central and Eastern Europe.

HIV and MSM

In Europe, sex between men is still the predominant mode of HIV transmission. Men who have sex with men (MSM) are the only key population not to see a decline in new infections during the last decade; new diagnoses increased by 33% compared to 2004.
Care models

- Infectious disease clinics
- STI/GUM clinics
- Primary care settings
- Drug treatment centres
- Community settings?
Predominant types of HIV testing site reported by EMIS Study Participants

- Green: Private practices
- Blue: Hospitals
- Brown: Community based testing sites
- Gray: Missing or excluded

Non-visible countries:
- Luxembourg
- Malta
Addressing the needs of PrEP providers

• Many potential PrEP providers do not yet know that it exists

• Some potential providers may not be experienced with antiretroviral treatment, sexual health counselling/risk assessment

• Implementing appropriate systems for follow-up and monitoring of PrEP users (STI testing, laboratory screening)

• Partnering with clinical societies, training, setting-specific guidelines, sharing of implementation practices, other support (hotlines, etc)
Proportion of gay male respondents who state that no medical staff/health care provider is aware that they are gay.
Ongoing and planned European demonstrations projects important to address remaining questions

- Who will request and take PrEP?
- How often (intermittent and/or regular dosing) and for how long?
- What are the optimal care models and referral pathways?
- Longer term effects on the users of PrEP?

- Adherence
- Uptake in the intended target group
- STI rates
- Quality of life and sexual health
Addressing the needs of PrEP users

• Many potential PrEP users are not yet aware that it exists

• Information provision
  • Is PrEP right for me?
  • Where can I access it?
  • Is it effective?
  • Is it dangerous?
  • PrEP-related stigma

• Adherence support
Scale-up takes time: new persons started on PrEP per quarter in the United States

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
Summary

• Momentum is growing in Europe with regard to the use of PrEP as part of a comprehensive approach to HIV prevention among some populations

• Some factors related to European health systems make decision on funding and implementing PrEP complex

• Actors in Europe have the opportunity to collectively address and document solutions to implementation challenges at policy, care provision, provider and patient levels
The role of community involvement in IPERGAY and other PrEP studies

Daniela Rojas Castro
September 18th 2015
Introduction

– Working with PLWH or exposed to HIV
– Informing, involving...and empowering the community/the communities
– PrEP, but also...access to treatment, health rights for migrants, educational intervention targeting injecting drug users, etc
Targets & Partners

- Politicians
- Institutions
- Advocacy
- Global mobilisation
- Community ONG
- Community based research
- Researchers and research agencies
- Health providers
- Actions on the field

Strategy

Community based research
- Researchers and research agencies
- Health providers
- Community ONG
- Advocacy
- Global mobilisation

AIDS
ACTIONS
75 sites and the net

seronet
Gay Bareback Zone.com
For Cum Addicts!!!
• AIDES asked for a “TU” for PrEP to the ANSM
• ANSM decides to create an independent group to analyze the possibility to open “TU” (of Truvada for PrEP)
• 2 commissions
  – Risk and benefits of PrEP
  – Deliverance framework (medical advice, reimbursement by the healthcare system,....)
  – What about the role of peers providing information and counseling?
ADVOCACY
Minister of Health June 2015

• She asked to ANSM and CNS to produce reports on PrEP to define the role of this tool in the global strategy of prevention

  – Results by the end of the year?

• Synergy with the Morla expert’s report
ADVOCACY
Pride 2015
Network of European Associations asking for PrEP

Fear no more!
Catalysing the empowerment of gay men for HIV prevention, treatment and stigma reduction in Europe

Activist consultation organised jointly by the European AIDS Treatment Group and UNAIDS
Brussels, 22-24 June 2015
COMMUNITY-BASED RESEARCH

• An opportunity to fulfill a **need** (survey 2009)
• A possibility to include and ensure counseling and **personal coaching** regarding sexual health
• Integration of a **psychosocial** approach in the biomedical project
• Social transformation
• Potential benefits of intermittent PrEP
  — Higher adherence: more convenient dosing regimen
  — Less health risks because of a lower drug exposure (kidneys, bones)
  — Cost-effectiveness
What else happens in Ipergay in addition to medical monitoring?

**Before the appointment**
- Questionnaire e-mailed to the participant

**Visit to an Ipergay center**
- **SH Coach:** Brief Sexual Health Counselling
- **Doctor:** Pre-test counselling, STI’s consultation
- **Pharmacist:** Trial Tablets & observance
- **Nurse:** Blood samples / STI Traitements, Vaccinations / Next appointment

**After appointment**
- **Phone Call:**
  - Post negative test counselling
  - Organization of a follow-up visit to the Ipergay center

**Follow-up**
- Focus Group
- Long-Term Counselling

Availability to requests / emergencies = phone – messages (SMS, WhatsApp) – emails

Thanks to Stéphane Morel for this slide
COMMUNITY-BASED SUPPORT IN THE ANRS IPERGAY TRIAL: IMPROVING ADHERENCE TO THE TRIAL AND ACCESS TO OVERALL HEALTH

1. The tools proposed by the community-based sexual health coach

In each centre, a community-based sexual health coach was part of the medical research team. Their close support model was inspired from the RESPECT model and the community-based practices and know-how which the CBO AIDS has built since 1994. Each sexual health coach is a reference point and privileged contact for about one hundred participants.

They build a long-term relationship with participants based on non-judgmental and confidential attitudes. At their disposal, they have an innovative toolkit of:

- Brief counselling sessions which are systematically offered to the participants at each visit during the follow-up, and the processing of negative test results on top of medical consultations;
- more in-depth counselling sessions on demand and a personalized follow-up proposal in case of positive STI test result;
- monthly self-support focus groups for the trial participants: a time for information and appropriation, renewal and collective development and for sharing experience;
- implementation of an on-line forum for sharing experiences and points of view, restricted to the trial participants;
- a hot-line availability of the sexual health coaches (can be reached by phone, text message or app) to adjust preventive responses and solutions in real time according to the needs of the participants.

2. The trial, the placebo pill and I: how to enhance clinical trial adherence and comfort?

- Peer exchanges at inclusion between the participant and the sexual health coach served to familiarize with the trial, while the choice of PrEP instead of other ARV strategies and previous results of PrEP trials. This was an opportunity for an initial appraisal of individual needs, especially concerning trial assessment.
- A trusting relationship was set up, ensuring participants had privileged access to the sexual health coach, able to provide relevant information, listen and relay their needs.
- The community-based support featured a better appropriation of the trial by the participant through individual counseling and self-support focus groups.
- The sexual health coach ensured the correct understanding of the trial’s regimen and worked on a personalized and targeted prevention strategy.
- In the open phase, community-based support was crucial for individual and collective appropriation of the trial’s results. Emerging needs were assessed (e.g., questions about adherence to PrEP). Coaching times were also opportune to share concerns about the end of the trial and the future framework for accessing PrEP in France.

3. My PrEP, my sexuality: how to embrace the sexual health field, how do I think "global"?

- Throughout the trial, time for support has increased awareness concerning STI prevention and allowed a better assessment of sexual risk according to sexual practices. The trial offered a privileged moment to talk about combined prevention on a regular basis, what is the place for condom, placebo, PrEP (at the time of open phase)! The aim was to focus on experience to promote a personalized risk-reduction strategy corresponding to participants needs.
- In the open phase, self-support focus groups were an opportunity to question the feeling of safety and its consequences, disinhibition (how to deal with it) and the possibility of increasing the quality of sexual life.
- Community-based support has the foundations for an increasingly autonomous multidisciplinary health path and focused on specific and clearly identified needs (referred to other health professionals: psychologist, addition specialist, sexologist, dermatologist, gynecologist).

Lesson learned

- The offer provided by community-based sexual health coaching has been the heart to promote a good understanding of the trial through peer exchanges and enable the adherence of participants.
- It has also raised the participant awareness of a global health approach.
- The present experiment is as such a major innovation. It seems essential to include community-based support in therapeutic trial and prevention policies in the future.
COMMUNITY-BASED RESEARCH

• To describe HIV negative people’s awareness of PrEP, their willingness and intention to use it
  – What populations are informed? What populations are willing to take PrEP? And what proportion of them intend to take PrEP?
  – What are the reasons for interested/intention of taking PrEP and vice versa?

• To describe informal PrEP use
COMMUNITY-BASED RESEARCH

- 3024 respondents
- Internet and paper survey
- Only 33.6% of respondents were aware of PrEP before answering the questionnaire
- Intention to use PrEP if available: mostly migrants and heterosexual men
- People at high or very high risk for HIV infection
- 4.5% informal use of PrEP
PrEP Knowledge
(N=2853)

- Femmes: 82.1%, n=185
- Hommes hétéro: 66.9%, n=172
- HSH: 46%, n=597
- Ech total répondants: 68.5%

520 Heterosexual men
1 036 Women
1 297 MSM
Statistically significance
4.5% (n=136) of respondents have already used PrEP at least once.

74.2% are MSM (n=98)
11.4% are heterosexual men (n=15)
14.4% are women (heterosexual and WSW) (n=19)

MSM are significantly more likely to informally use PrEP (7.6% vs. 2.9% of heterosexual men, p<0.001)

<table>
<thead>
<tr>
<th>Informal PrEP use</th>
<th>YES</th>
</tr>
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<tbody>
<tr>
<td>Women</td>
<td>1.8%</td>
</tr>
<tr>
<td>Heterosexual men</td>
<td>2.9%</td>
</tr>
<tr>
<td>MSM</td>
<td>7.6%</td>
</tr>
</tbody>
</table>

Those reporting to be at high or very high risk for HIV infection are significantly more likely to report informal PrEP use (35.9% vs. 10.3% of people not using PrEP; p<0.001)
COMMUNITY-BASED RESEARCH

Prepage Study

30 interviews

Get information on:

– The experience and the needs of people who use "informal PrEP"
– The experiences and expectations of informal PrEP users in order to design an appropriate delivery framework

Partners:
AIDES
ANRS (Agence de recherche ANRS (France Recherche Nord&Sud Sida-HIV Hépatites))
INSERM (Institut national de la santé et de la recherche médicale)
Groupe Hospitalier Hôtel Dieu
Next Steps

• **National advocacy strategy:**
  – Open-label PrEP in France
  – Medical working group to establish guidelines/recommendations concerning informal PrEP use (Société Française de Lutte contre le SIDA)
  – Showcasing the coaching/support provided by peers
  – AIDES has decided (12/13 September 2015) to deliver PrEP and to refer informal PrEP users for follow-up (in partnership with medical staff)

• **European advocacy strategy:**
  – ECDC - guidelines
  – EATG
  – European Medicine Agency
  – Gilead (Marketing authorization for prevention use of Truvada…) but also other pharmas developing new PrEP drugs (Jensen, VIIV)

• Scientific valorisation: Ipergay, FlashPrEP, Prepage...
• Develop a **Flash PrEP EUROPE**
Informing, involving, empowering, is more than just recruiting...
The time for debate on the effectiveness of PrEP is over.

Merci...
drojas@aides.org