

PrEP in Europe 2019
Day One

- 1) Science of oral PrEP - by AVAC
 - PrEP works when taken - for everyone if taken daily
 - For MSM when taken on demand
 - But this is for people who can access PrEP - what are alternatives or different schemes?
 - F/TAF is not inferior (discover) better bone health and renal functions (worse cardiovascular and obesity though, more expensive - under patent) - not approved for receptive vaginal sex
 - Once monthly pill - my-8591
 - Long acting injectables
 - Will people come for the shot?
 - Drug tail? Protective or resistance
 - Excludes people with butt implants
 - 3 vaccines trials (Mosaico to watch in Europe)
 - Broadly neutralizing antibodies
 - Infusions from long term non progressors
 - Vaginal ring - reduces risk by 56%, approved for Africa
- 2) Does PrEP ever fail and if so, why? - by MES
 - Top barriers when prescribing in Poland
 - Not enough knowledge 72%
 - Lack of experience 56%
 - Not covered by insurance 17%
 - In the world - 69% cost and no coverage by insurance
 - Sociological barriers
 - Do I need it? Does it work? Where can I get it?
 - In chemsex users study in Poland - out of 107 msm only 10% used PrEP
 - How to test correctly for sexually active population?
 - Adherence? Older men take pills more responsibly. The longer the person takes PrEP, the less adherence is observed
 - Why people quit PrEP?
 - Monogamous partner
 - Increase condom usage or decrease nr. of sexual partners
 - Less alcohol or drug intake
- 3) PrEP and STIs - Gus Cairns
 - HIV incidence decreases, STI seem to increase
 - But when did STI incidence start increasing? Not when PrEP was implemented, but when people stopped dying of HIV
 - More likely STIs were at a historical low in the 90's
 - And not all STIs have increased - only syphilis and gonorrhea
 - So - does PrEP **independently** increase risk of STIs?
 - Victoria state study: naive vs. experienced PrEP users
 - Slight increase in people with previous experience
 - Evident increase in people new to PrEP
 - Therefore it was concluded that high STI incidence was due to more frequent testing that finds STIs more often as patients have to get counseled
 - Depends what you look for - logically, people at higher risk of contracting HIV are at higher risk of contracting other STIs than "low risk" population
 - PrEP is also an incentive of coming to the STI clinic
- 4) How to get PrEP where you can't get PrEP from the medical system - by Greg Owen
 - iwantprepnw.co.uk - why take it, where to get it, how to discontinue, and also offered purchase
 - Is online generic PrEP real?
 - Prepster 2018 - 14 generics, 6 online sellers - no fake preparations
 - 56 Dean St - 234 PrEP users, no fake preparations
 - greencrosspharmacy.online - sends to over 50 countries
 - Need to check import regulations, legality of promoting PrEP

- What you need when starting prescribing PrEP? - the ONLY essential thing is 4th gen hiv rapid test
- Hep B ideally, Renal function test would be great
- Mags Portman PrEP access fund
 - Can not get PrEP from medical system
 - Meets clinical eligibility
 - Meets financial eligibility
 - People get a code, which patients use to get PrEP at the pharmacy (they legally can't give PrEP to people or buy it for them, but they can give them a code)
- PrEP shop at 56 Dean St
- But we need to campaign for free/very low price PrEP

5) Discussion panel

- 250 000 people use PrEP in the USA (out of 1.3M eligible at risk persons)
- PrEP is a "white well-off gay on the coasts" thing where healthcare provides it. Elsewhere in risk communities (southern states) of gay men of color don't have access to healthcare let alone PrEP
- 40% of transmissions occur in the first year of infection (cdc)
- **Combination prevention**

Day Two

Open society fund - případný kontakt?

6) Status of PrEP implementation

- 160 000 people diagnosed in 2017
- 80% diagnosed in the eastern region
- 47% of those infected in the western region were born outside of the country
- Since 2015, infection rates between MSM have been declining
- Sustainable development goals by ecdc
 - By 2030 - no new infections, zero aids deaths and zero discrimination
 - By 2020 - fast track targets - 75% reduction as compared to baseline in 2010 - in EU we are at -15% as of now, wider European region is increasing however
- Why aren't you implementing PrEP? Cost is nr. 1 reason
- In wider European region, out of 23 countries, price per month of PrEP range between 850 to 3.25\$
- Hornet 2017 study - government couldn't provide data in France
 - 17% of those not on PrEP were diagnosed with STI, while 48% of those currently on PrEP were diagnosed - people at risk are protecting themselves, they are appropriately assessing their risk when becoming candidates
- PrEP gap - the difference in percentage point between the people who are on PrEP vs. those who would like to be on PrEP - in wider European region anywhere from 48% to 4.3%
- Between 420 000 to 610 000 MSM in Europe would like to use PrEP but can't access it - what is this for women, migrants, trans people?
- Testing gap - 1 in 5 PLHIV are unaware of their status in Europe
- Treatment gap - not everyone is on optimal treatment

7) Is PrEP working? What about U=U? by Valerie Delpech

- PrEP works, is a key prevention tool and is **cost saving**
- PrEP works best in combination prevention settings, better in community settings
- Cost effectiveness - depends on PrEP price in country, ARV price, nr of people at risk
- What does the decrease in incidence actually mean? Need for local context.
- The impact of PrEP will depend on:
 - Adherence
 - Getting monitored
 - Getting treatment if seroconverted
 - System factors - political will
 - Demographic factor - context of the epidemic

8) PrEP cost, drug cost, cost effectiveness

- Cost - 62 people who take PrEP to cover one PLHIV
- Methods of cost effectiveness calculation

- Prevention on individual level - at least 85% decrease in risk
- Prevention on population level - people who use PrEP also protect their sexual partners
- Measuring effectiveness - based on Quality adjusted life years
 - Discounting 3% over 40 year horizon
 - Annual costs: PrEP plus test, people's work

9) PrEP in hostile environment

- In the EECA, 70% new diagnoses are from Russia
- Systemic problems of hiv prevention among msm in Russia
 - No epidemiological studies
 - Hostility towards lgbti people
 - HIV service organizations face difficulties due to "foreign agent" law

10) How PrEP gave us the lifestyle we deserve - by Dani Singer

- "PrEP represented sexual freedom"
- "Opening new possibilities"
- "Bringing the thrill back to sex"
- "Opens an honest conversation"
- "I didn't realize I was taking an «antidepressant», all those years of fear and shame were suddenly gone"

11) E-PrEP: e-consultation - by Daniel Hilt

- E-PrEP project in rural France
- AIDES - community based association fighting HIV and hepatitis, 76 centers (in Caribbean too), member of coalition plus - member of coalition plus
- Why e-PrEP in region Centre-Val de Loire? Hidden epidemic and difficulty of access to care (distance, time of appointment, ignorance my medical staff, stigma)
- Solution? Internet. How?
 - Digitally connect - target populations, dating apps
 - Offer e-counseling on sexual health - Gruveo, WhatsApp, Skype. Postal dispatching.
 - Jan-jun 2019: 346 e-interviews.
 - Qare - medical consultation platform, will be used for e-PrEP from January
 - Free
 - Smartphone
 - Secure
 - Schedule management
 - SMS reminders
 - E-recepty
- Problems: Laboratory and STI tests? Human Resources?

12) Cultural politics of PrEP activism by Freek Janssens

- Now PrEP is not available for everyone in the Netherlands
- Professionals agree on PrEP, the community is split on PrEP and activists face resistance

13) Risk compensation and biomedical prevention - by

- Moral judgements on sex counseling!!! "We won't stop syphilis if we keep the mindset that nice people don't have syphilis, nice people don't talk about syphilis"
- PrEP outcome: should be defined as HIV decrease, NOT STI increase
- "Obsession with risk compensation impedes access to PrEP"

14) Challenges of PrEP use in Europe beyond mere access by Kai J. Jonas

- Formal access is not yet a given in Europe
- GETTING INFORMAL PREP USERS BACK INTO FORMAL CARE
 - Thousands of users in Europe
 - Some of them regularly test, etc., this it's a successful therapy
 - Switching to formal PrEP is often not attractive
 - PULSE (Thailand) survey: 55% it's too complicated, 64% it's still cheaper in other countries, 41% can't afford co-payment, 17% healthcare not gay friendly, 22% stigmatization, 45% community - my friends get it informally at the community center too
- SEROCONVERSIONS ON PREP

- casual user - suboptimal regimen, unclear status at initiation
- Perfect user- for some reason stops and then immediately gets infected
- The seropositive user at initiation
- PREP SORTING
 - PLHIV and PrEP users prefer other PrEP users for sex
 - People who don't use PrEP prefer monogamous people who do not take PrEP
- HIV PREVENTION AFTER PREP
 - what to do with people who decide to discontinue PrEP?

15) Good practice amongst queer men of color

- men of color are less likely to take prep
- Need for more specifically targeted campaigns
- Lack of research for men of color (in local settings)

16) Relovution - msm Caribbean community

17) Programs for latinos in uK

- growing community
- Higher hiv prevalence
- Incidence doubled
- 50% infected in Uk
- Language barrier
- Immigrant status
- Online counseling
- Video series (vox pop, Core series on prep, expert videos, testimonials)
- Chat function by Metro Charity
- What worked: diverse mix of volunteers

18) Friendly doctors and the alliance between medics and the community

- Urge politicians to say the truth

19) Pan of prepu - by Lukasz Sabat

- Subtitles for us PrEP videos
- Talks at krakow pride
- Fetish and sex shop blogs campaign
- Big interview in lgbtqi magazine Replika
- Pan of PrEP-u

20) Prepster

- We already know the answers about PrEP
- Targeting the campaign and tailoring the access - people other than white msm are rarely informed about PrEP
- Work driven by PEERS!!! entre iguales
- Innovation?? Is it always good
- Prepster invites everyone to replicate any of the campaigns they used, to adapt them and collaborate

21) Spreading the word: messaging for PrEP

- PrEP for cis women
- RISK PERCEPTION
 - 2,5% of black African men and 4,7% out of black African women are estimated to live with HIV
 - 38% of new diagnoses among heterosexuals account to black African persons despite only being 2% of the population
- Having health in your own hands

22) Developing PrEP programmes for women

- Necessary to integrate PrEP with other health services and reproductive rights programme
- Programme for all self identifying women
- High importance of training of volunteers

Multiple PrEP Regimens - Cis MSM

| | | | |
|--------|------------|--------------|---|
| World | WHO | Daily | start = 7 days / stop = 28 days |
| | | Daily | start = 2 tablets / stop = 2 days (since 07/2019) |
| | | Event driven | start = 2 tablets / stop = 2 days (since 07/2019) |
| Europe | EMA | Daily | 1 tablet/day / stop = NC |
| | EACS | Daily | Pdf 1 tablet/day, Vimeo start 7 days / stop 28 days |
| | | Event driven | start = 2 tablets / stop = 2 days |
| France | ANSM | Daily | 1 tablet/day / stop = NC |
| | HAS | Daily | start = 7 days / stop = 2 days |
| | Morlat | Daily | start = 7 days / stop = 28 |
| | HAS/Morlat | Event driven | start = 2 tablets / stop = 2 days |



Some guidelines don't explain **how to start or stop PrEP**

PrEP users learn about different regimen and **get confused**



PAGE 3

- Large array of activities (prides, carnivals, Muslim forum, film screenings, hairdressers events)

23) Nigerian female sex workers and PrEP: lessons in the inclusion of vulnerable populations -by Jennifer

- Community led approach
- Action "Ladies" - 2015 onwards
 - 100 women each night (decrease due to police raids)

24) Sexual health for trans men

- Trans = people who do not identify with their gender assigned at birth, umbrella term for trans men, trans women, genderqueer, trans non-binary, etc.
- Women = both trans and cis women
- Transsexual is a problematic term
- Trans people are 5x more likely to be living with HIV
- 19% of black trans women in US are HIV+
- 33% of US TRANS SURVEY experienced discrimination you healthcare provider
- Trans men usually aren't part of sexual health talks - discrepancy in power dynamics
- Trans men often have issues that cis gay men don't see them as men
- Trans people are less likely to undergo preventive testing
- Trans men have difficulties saying "no" in sexual context
- Trans men wit vaginas on testosterone experience vaginal wall thinning and it produces less mucous layer - higher risk of STI

Day Three

25) Focusing on cis and trans women and trans men

- High risk, vulnerable population - due to receptive sexual techniques
- Difference due to: epithelium, microbiota, hormones, immune cells
- Rectum - dendritic cells acts a transporters for HIV virus
- In vaginal tissue there are more steps of cells from mucosa to blood circulation, drains to lymph nodes, unknown on which level TDF/FTC acts
- No effect of oral contraception on PrEP blood levels

- No to very low effect of feminizing hormones on blood levels in Thailand study
- Microbiota - certain bacteria are able to metabolize tenofovir in gels
- Topical PrEP - vaginal gel - low efficacy, bad adherence
- Vaginal ring - infused with dapivirine, RING and ASPIRE studies
- Systemic PrEP
 - Tenofovir, after 24 hrs single dose: high levels in rectum, low in vaginal tissue
 - Emtricitabine: opposite effect
- Focus on tenofovir alafenamide
 - Models in macaques and vaginal levels and hiv transmission risk
 - No studies in cis women
- Cabotegravir injections as alternative to TDF/FTC
- Trans women - iprex study. Distressing at first due to high infection rate, but no one who had detectable plasma levels got infected - most likely due to poor adherence
- DISCOVER study - MSM and trans women - equal efficacy
- Conclusion: proven efficacy of TDF/FTC for ALL POPULATIONS
- Difference between genders is due to difference in adherence

26) Scientific story for women and PrEP -by Gilead

- Since 2014, no increase in percentage in new PrEP users in the USA
- Many women don't feel the need to use condoms after childbirth
- Highest susceptibility to hiv transmission is postpartum due to cervical thinning and hormonal changes
- In women, there is pressure from friends/family to avoid PrEP (unlike often MSM)
- Women tend to underestimate their risk of HIV infection
- Clinical trials in women are very difficult due to low usage of PrEP and difficulty finding the cohorts

27) MSD's ongoing efforts in HIV biomedical prevention -by Merck (MSD)

- Phase II trial of Oral Islatravir - once monthly pill due to very long half life

28) Long acting cabotegravir (CAB LA) for PrEP -by viiv

- Integrase inhibitor
- Both for treatment and prevention
- Long half life and highly insoluble
- One i.m. gluteal injection every 8 weeks
- 42% of women had detectable levels of CAB after 76 weeks of injection
- It takes twice as long to clear the drug for women, 15% more time for people with BMI 30 and higher
- HPTN 083 (4500 msm and TGW) and 084 (3200 sub-Saharan young women)
 - Oral lead in, TDF/FTC controlled, to prevent reactions to CAB
 - Step two - injection phase, double blind, double dummy design
 - Step three - oral PrEP for 48 weeks to cover pharmacokinetic tail
 - 63 sites across 13 countries
 - Both trials are endpoint driven. Non-inferiority study in 083, superiority trial in 084
 - HPTN 083 recruitment is complete. 66% <30y.o., 12% TGW, 50% black MSM
 - HPTN 084 77% recruitment complete
- PK tail - risk of resistance? Use in pregnancy?
- Need for TB therapy adjustment due to interactions

29) PrEP regimen - how to empower users to adjust PrEP to evolving sex life -by Stephane Morel

- Supporting PrEP adherence - how to translate scientific language into daily life and explain PrEP regimen the simplest way possible
 - How to start and stop PrEP
 - What to do when a dose is missed
 - Adjusting PrEP to adjusting sex life and frequency
- Lot of confusion of different regimen recommendations (WHO, EMA, France)
- *Daily* or *on-demand* - obsolete terms
- Better is *starting* and *stopping*

30) PrEP.Point demonstrates a large reduction in HIV incidence -by Michael Meukbroek

- Working with peers - MSM physicians, nurses, professionals
- Point of care technology
- Studies 493 people
- Informal 702 people (360 made at least one follow up visit)
- Retention 95,9%, most left due to relocation, only two people had to stop due to adverse side effects
- 4 seroconversions
 - Stopped medication
 - Infection in serologic window
 - 2 improper regimen
- Expected HIV infections: 17 (HIV incidence in Checkpoint 2,11 person-years) -> 76,5% reduction

31) SOPHOCLES - P4G

- Recruitment in Athens Checkpoint
- 74% have been tested in the last year, 25% were diagnosed with sti in the last year, had a median of 10 sexual partners in the last 6 months
- 30% showers symptoms of depression
 - Of those chosen, high risk: median age 33,5; median nr of sexual partners 30, group sex 96%, chemsex 66,7%
- 1 seroconversion (diagnostic window at initiation)
- The program only finished its first 6 months and continues

32) PrEP in Georgia by Equality movement

- Very difficult situation due to homophobia
- Targeting risk groups
- Based on assessment, they derive clients to HIV/AIDS department
- 300 persons
- aug 2018 - dec 2019
- Free of charge
- 48% aged 18-24
- 58% are employed
- 54% live with parents
- 23% reported 10 or more sexual partners in the last months
- 75% experience in group sex
- 66% drug use (including cannabis)
- Barriers?
 - HIV stigma and discrimination
 - Homo- and transphobia
 - Institutionalized stigma
 - Lack of hiv related knowledge
 - Geographical access

33) Situation in Poland

- Very few *real* sex clinics and STI specialist
 - Aggressive and passive aggressive homophobia
 - Over 71% of doctors working with HIV patients would be willing to work with PrEP and 52% would be willing to offer it at their workplace
 - 80% of clients were diagnosed with an STI in the last year
 - The ones who had the most condomless sex got tested most frequently
 - 80% wanted free PrEP, but the median they were *willing* to pay was 25€
 - 2000 PrEP users in Poland, 99% msm
 - Of those 500 get PrEP online
 - PrEP clinics became places of STI testing (by PrEP clinics the authors meant a department of the Infectious diseases ward)
 - Facilitators: local gay friendly doctors and scientists; MDs as part of gay community
- New speaker*

- Starting point
 - Social taboo around sex
 - Hospice political and social environment
 - Community misunderstanding around PrEP
 - Public health officials doesn't support PrEP
 - Financial resources
- COMMUNITY INTERVENTION ASSUMPTIONS
 - Engages community
 - Culturally competent
 - Focuses on at-risk sub-communities - potential user identification (questionnaire criteria)
 - Awareness raising - ideally by well known personas, high traffic websites, cultural institutions (cinema festivals, etc.)
 - Easy access

34) PrEP campaign in Ukraine

- 148 people volunteered,
- 100 participated
- 24 discontinued

35) PrEP in France

- Approx. 18 000 people on PrEP
- -16% decrease of hiv in Paris, -28% decrease of MSM born in France (compared to 2015)
- PrEP needs promotion - pamphlets, videos, **billboard in metro** (used Chicago's campaign with their consent)
- Supporting peers
 - Facebook group for PrEP facts, also self support
- Le SPOT Longchamp
 - Community based sexual health clinic
 - Promotion of PrEP to **EVERYONE** who comes four testing
 - 420 people on PrEP
 - In MSM, focus on chemsex consultation

36) Western Europe (late): Spain

- PLHIV 140 000 - 170 000
- EMA approved the use of PrEP by the ministry of health "blocked" it
- In Oct 2019 success - the ministry approved the implementation of PrEP covered by the health system
- At the same time, condoms are promoted

Poster

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MI counselling has been introduced in the STI clinic of the Public Health Service Amsterdam in 2006.

Service providers requested additional guidance during consultations addressing PrEP use and condoms.

Content of the manual

The manual gives a short introduction of MI. Here are some examples from the manual.

1 Inform about PrEP

"You came today to talk about PrEP. It is important for you to protect yourself against HIV. What do you already know about HIV and PrEP?"

2 Starting PrEP

"These are possible topics that we can discuss. If we are missing an issue you find important, we can add that. For example, correct use of PrEP; side effects; STI; condom use; drugs; mental health/well-being; (sexual) health." (fig.2)

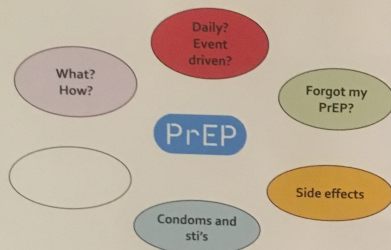
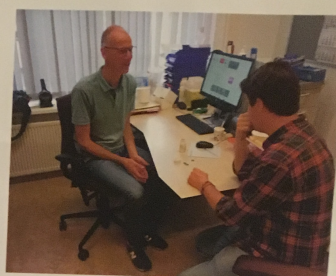


Fig 2. Agenda Setting for PrEP consultations



3 Follow up of PrEP

"We know from experience that condom use changes in some people who start with PrEP. You are now protected against HIV. What will you do?"

4 Stopping prep

"How do you feel about the fact that you will soon no longer be taking PrEP?"

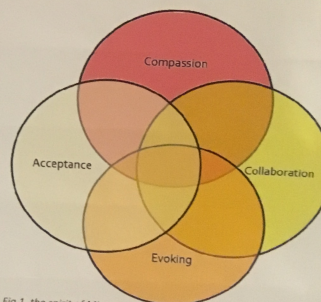


Fig 1. the spirit of MI

Discussion

Counselling with MI helps health care providers to evoke their ambivalence and reduce possible barriers towards PrEP care.

Health care providers benefit using this manual talking to clients about PrEP in a non-judgemental way.

MI may help stakeholders in their communication with health care providers on the subject PrEP.

MI is a way to keep your clients coming back to you.

If you would like a copy of the manual kedjong@ggd.amsterdam.nl