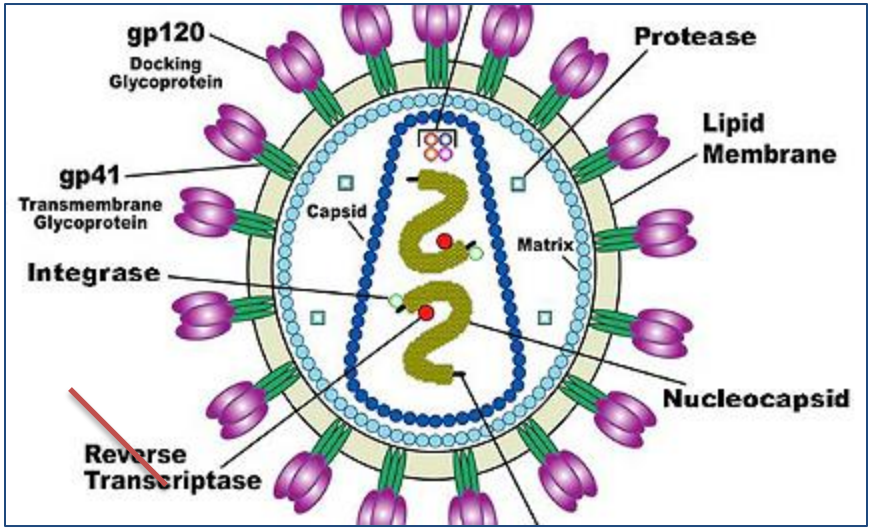

Moving from PrEP Science to Practice: Update and Clinical Scenarios

Oliver Bacon
oliver.bacon@ucsf.edu
David Evans
devans@projectinform.org

PROJECT INFORM

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Capacity Building Assistance in High-Impact HIV Prevention for Health Departments

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Agenda

- Why PrEP?
- Update on Efficacy Studies: 5+2
- How to PrEP
  - Generic model of a PrEP program, by visit
  - Counseling
  - Navigation, Financial Issues
- Scenarios

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What is PrEP?

- FDA approved emtricitabine/tenofovir (FTC/TDF, or Truvada®) 16 July 2012 for use as PrEP in combination with safer sex practices to reduce the risk of sexually-acquired HIV infection in adults at elevated risk
- Taken **daily** regardless of plans for sex
- As part of a comprehensive HIV prevention plan
- *PLUS* regular monitoring for HIV infection, STIs, drug safety, adherence

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Why New HIV Prevention Tools are Needed

- Despite testing, counseling, condoms, and ART, 40,000-50,000 new infections annually in the U.S.

- Incidence especially high in certain U.S. populations
  - Men who have sex with men (MSM)
  - Transwomen (FTM)
  - Women in the Southeast
  - Racial and ethnic minorities, especially youth
  - Injection drug users (IDU)

- Incidence far higher in Sub-Saharan Africa, Southeast Asia, Eastern Europe

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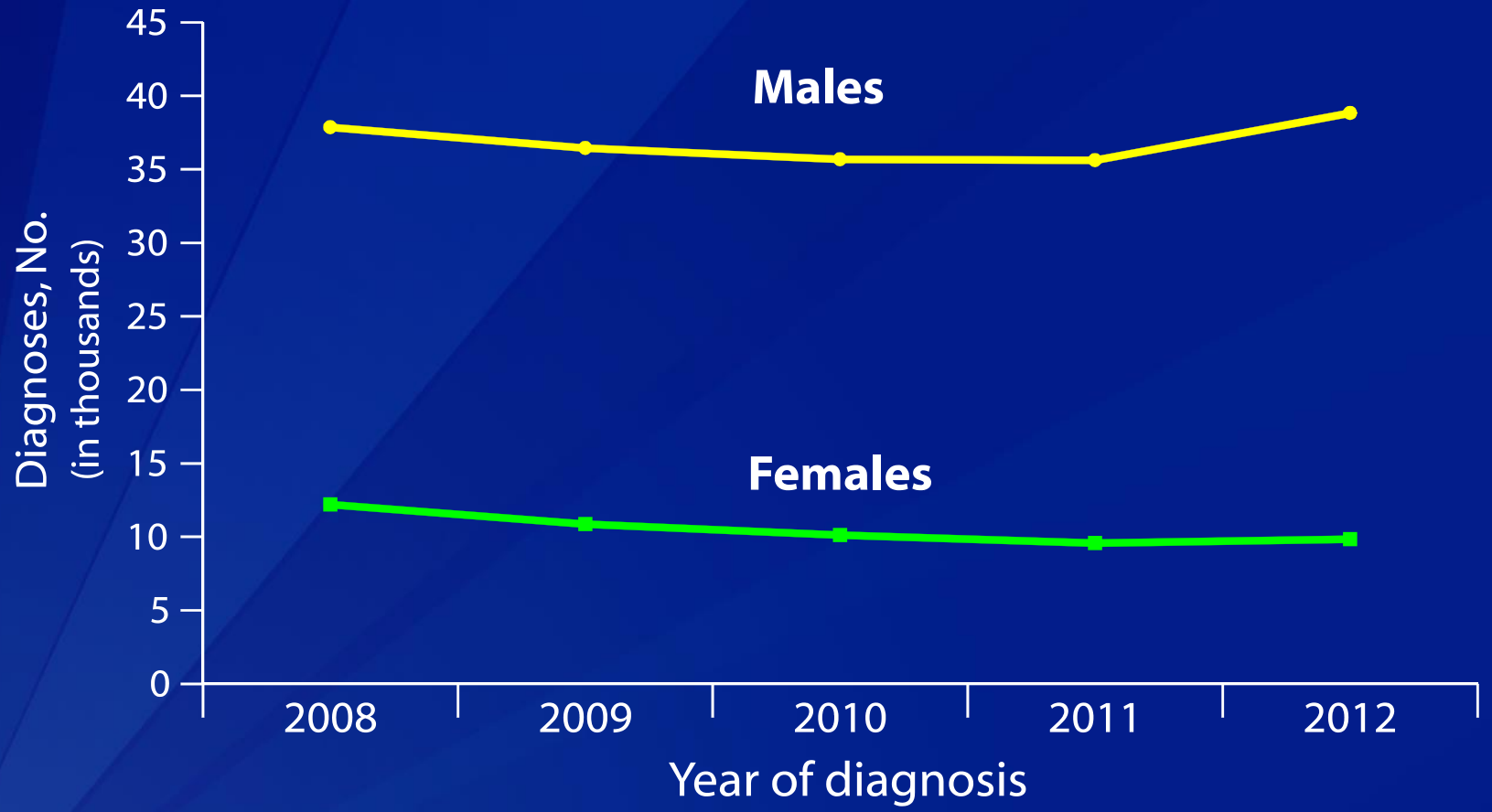
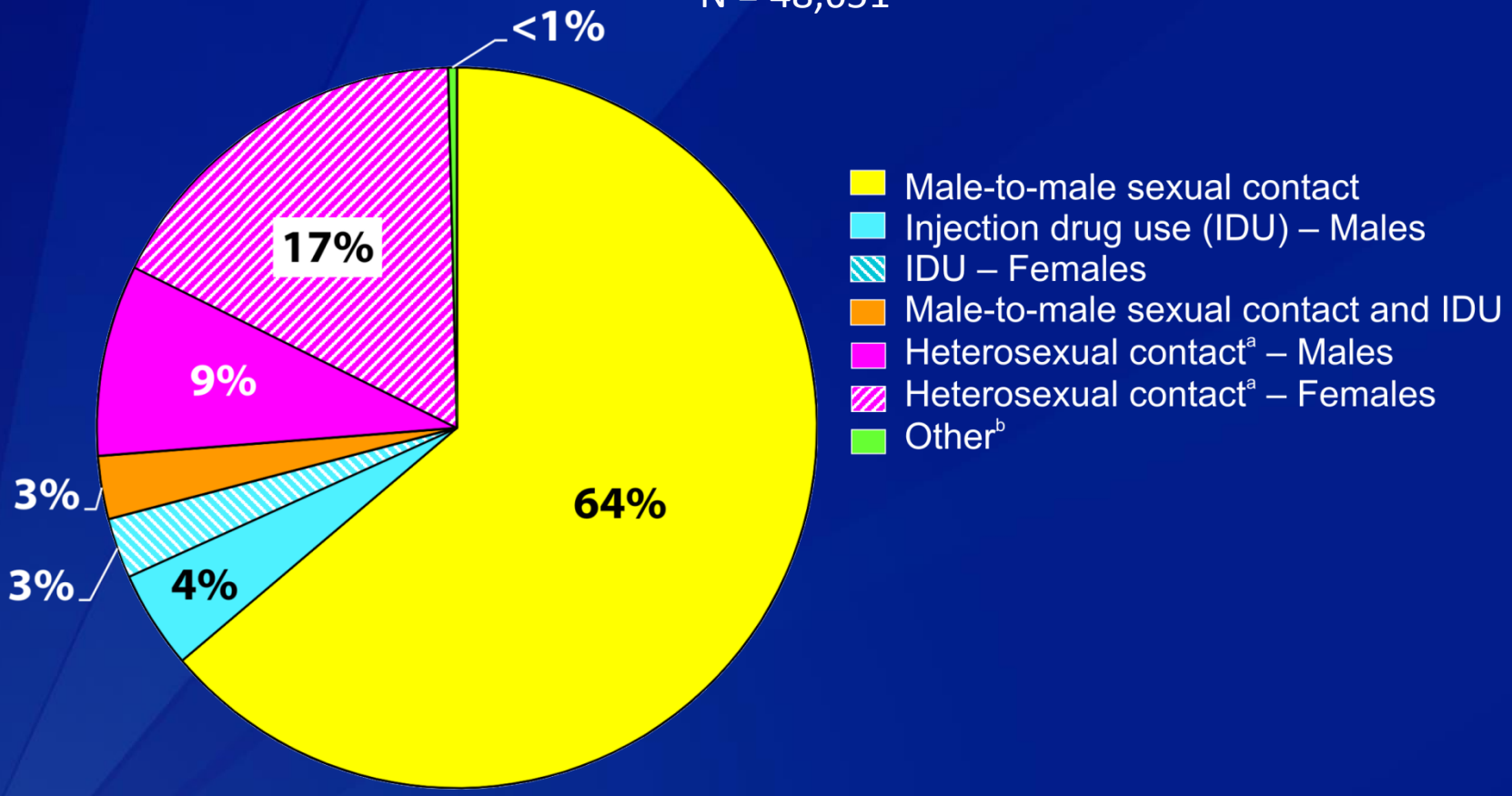
Diagnoses of HIV Infection among Adults and Adolescents, by Sex, 2008–2012—United States and 6 Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2012—United States and 6 Dependent Areas

N = 48,651



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

[a] Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

[b] Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.

Current HIV Prevention Methods: where are the gaps?

Method	(+)	(-)
Testing/Counseling + Condoms	Counseling: individual benefits? Condoms: 67%-80% efficacy if used correctly, consistently	Condom **efficacy drops off quickly if not used correctly, consistently** Inconsistent use no more efficacious than nonuse in recent CDC modeling study; 16% consistent use in US MSM
ART as Prevention ("TasP")	96% risk reduction in serodiscordant heterosexual couples (HPTN052)	**-Does not protect partners of infected-unknowns -requires higher testing, linkage, retention than current rates** -intermittent viremia?
PEP (Post-exposure Prophylaxis)	80% risk reduction (AZT monotherapy in occupational exposure)	-underutilized -requires initiation within 72h of recognized risk
Serosorting: • **"Positive:" HIV+ only have condomless anal sex w other HIV+** • **"Negative:" perceived HIV- only have condomless anal sex w other perceived HIV-**	• Positive serosorting: limits HIV transmission if both partners truly HIV+ • Negative serosorting: Better than nothing? Maybe?	Depends on: • Both partners' **accurate** understanding of status • Frequent testing of HIV- • No recent exposure since last negative test

If Effective, PrEP may:

- Provide a partner-independent prevention method
  - totally controlled by the user
  - independent of the state of mind immediately prior to and during sex

- Fill gaps in current prevention methods

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PrEP and the test/treat model

I. Universal, accessible HIV/STI testing
-Frequency determined by risk
-Testing for acute infection in high-risk populations/settings

IF (-)

IF(+)

III. COMBINATION PREVENTION
- Condoms and Risk Reduction coaching
- Referrals for Substance use treatment, Mental health care
- PEP for occasional exposures
- PrEP for Pts with elevated risk:
  - Inconsistent condom use
  - Multiple partners/non-monogamous steady partnerships
  - Serodiscordant partners including periconception
  - h/o Rectal STIs, PEP

II. IMMEDIATE ART
- Eliminate OIs/AIDS
- ↓ nonAIDS complications
- ↓ transmission to partners

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PrEP Efficacy and Safety

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TRIAL	POPULATION	LOCATION	Active arm(s)	EFFICACY If drug levels=High Adherence
iPrEx	2499 MSM and MTF	South America, USA, Thailand, South Africa	FTC/TDF	**44%** (95% CI 18-60) *48 vs. 83* **>90%**
TDF-2	1219 heterosexual men and women	Botswana	FTC/TDF	**63%** (95% CI 21-83) *9 vs. 24*
Partners PrEP	4758 serodiscordant heterosexual couples	Kenya and Uganda	FTC/TDF TDF	**73%** (95% 49-85) **90%** **62%** (95% CI 44-81) *13 FTC/TDF, 17 TDF,* *52 placebo*
FEM-PrEP	2120 heterosexual women	Kenya, Tanzania, Zimbabwe, South Africa	FTC/TDF	**No difference** *33 FTC/TDF vs. 35 placebo* *Stopped early due to lack of efficacy*
VOICE	5000 heterosexual women	Uganda, Zimbabwe, South Africa	FTC/TDF TDF Vaginal TDF gel	***No Difference***
Bangkok IDU	2413 IDU	Bangkok	TDF DOT *or* monthly visits, by choice	**48.9**% (95%CI 9.6-72.2, P=0.01) **70**% (95%CI2.3-90.6, P=0.04)
PROUD	545 MSM Q3m visits	Public GUD clinics in UK	Immediate vs deferred (12m) FTC/TDF	***86% (95%CI 62-96, P=0.0002)*** ***NNT=13***
IPERGAY	400 MSM Q2m visits	France, Quebec	Pre/post sex FTC/TDF vs placebo	***86% (95%CI 40-99)*** ***NNT=18***

Facilitators and Barriers to Adherence

Facilitators

- Altruism towards community
- Regular contact with study staff
- Open, nonjudgmental relationship with staff
- Accurate information about side effects and mitigation, how to handle missed doses
- Prior pill-taking (vitamins, other daily meds)
- Having a predictable daily routine

Barriers

- Predictable disruptions: travel
- Unpredictable disruptions: illness, stress, changes in mental health/job/housing
- Not sleeping at home
- Intentional skipped doses
- Stigma (hiding pill taking)

Gilmore et al. *AIDS PATIENT CARE and STDs*: 27(10), 2013

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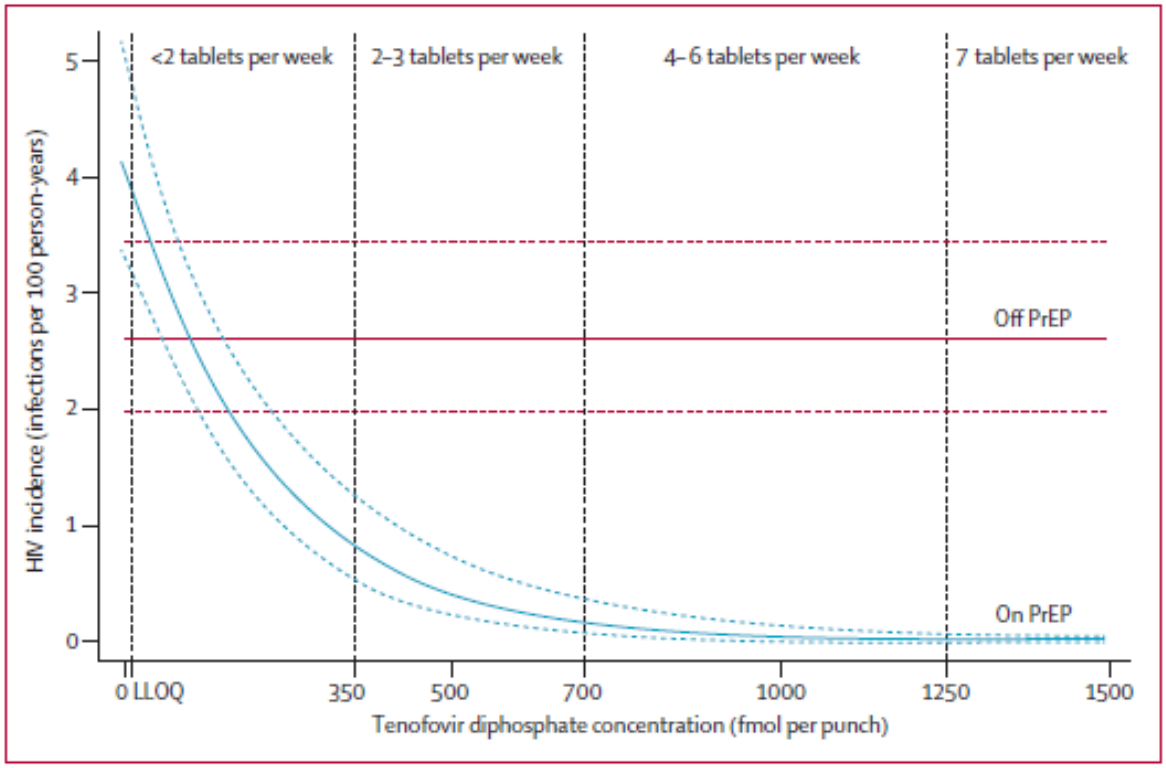
Adherence, Drug levels and Efficacy



Dosing	Estimated PrEP Efficacy
2x/week	76%
4x/week	90%
Daily	99%

Anderson PL. Sci Transl Med 2012;4:1-8.

Grant RM, Anderson PL et al. Lancet Inf Dis 2014

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PrEP Efficacy: Summary

- PrEP found to be moderately to highly efficacious in MSM, MSW, IDU
  - Highly efficacious in those who take it consistently
  - Adherence is the key variable: doesn't have to be PERFECT, but has to be better than good (for rectal sex)
  - How long to continue after last exposure?
  - Implications of IPERGAY still unclear: was this really just imperfect daily PrEP at 4 pills/week? Await further data……..

- Efficacy results in women mixed
  - Adherence is a major factor
  - Differential cervicovaginal vs rectal tissue penetration?
  - ?20 days to maximal cervicovaginal levels?
  - Perception of risk?
- Do women need to be *more* adherent than men?
- Need more data in Transwomen: effect of hormone therapy, adherence, uptake

CDC. *MMWR Morb Mortal Wkly Rep.* 2011;60:65-68. Grant RM. *N Engl J Med.* 2010;363:2587-2599.
Baeten J. Annu. Rev. Med. 2013. 64:3.1–3.14

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PrEP Safety: Summary

- Safety (vs. Placebo) *
  - Studied rates of death, serious adverse events, and laboratory abnormalities
  - no significant difference in kidney toxicity;
  - increased nausea and wt loss in FTC/TDF (P=0.04 for both)
  - small but sig. decrease in bone mineral density (BMD), without difference in fractures

- PrEP was well tolerated*
  - Adverse effects occurred in minority of subjects
  - GI adverse effects (eg, nausea) more common in those receiving PrEP than placebo
    - Occurred in < 10% and primarily during the first month only (PrEP "start up" symptoms)

*data from iPrEx, but similar results reported in other RCTs

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How to PrEP (in 2014/2015)

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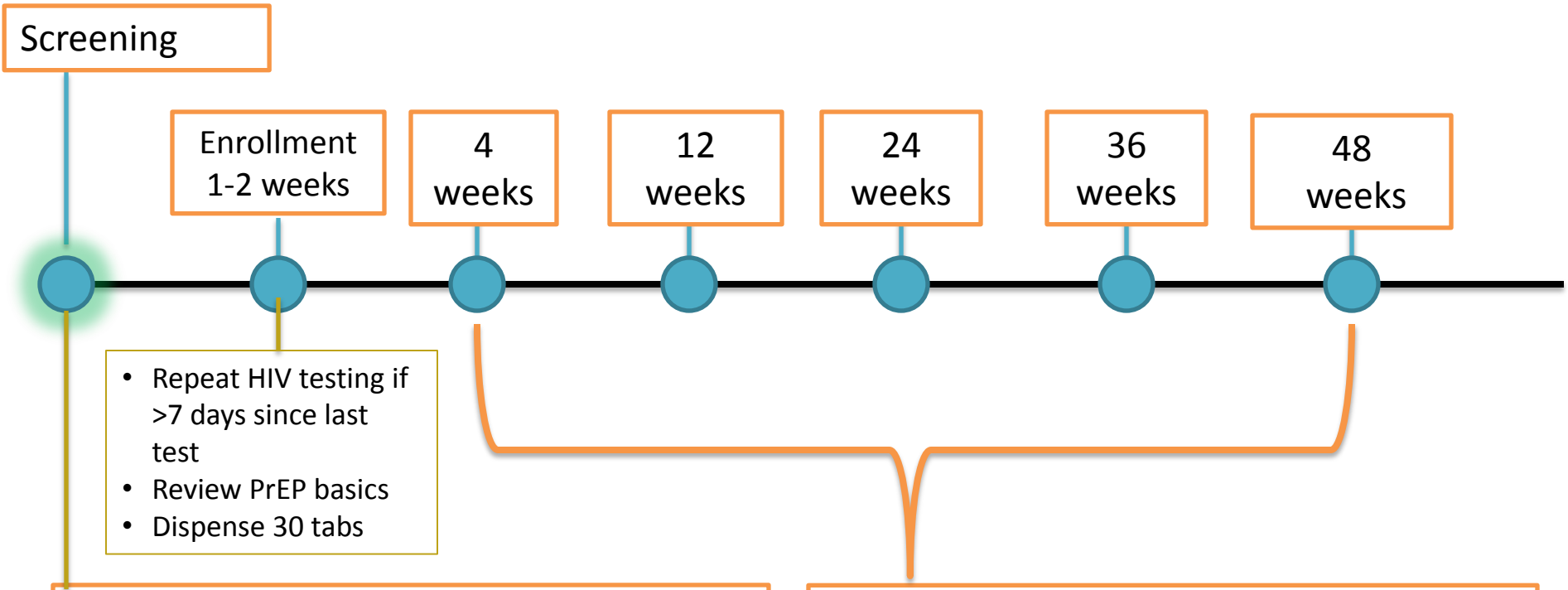
Sample PrEP Visit Schedule



First Visit: Assessment

- Sexual Risk Assessment
- Basic Medical History, exam
  - Sx of acute HIV?
- PrEP Basics: how it works, adherence, side effects
- Labs: HIV, STI, Safety (renal function, HBV)
- Navigation services: Provider/Clinic referrals as needed; Financial Case Management

Follow-up:

- Symptom review: Sx of acute HIV?
- Assessment, counseling:
  - Behavior
  - Adherence
- HIV testing
- STI testing
- Renal function testing
- Dispense 90 Tabs

Taking a Sexual History

The 5 P's

- Partners (#, gender) over given time
- Practices (oral, anal, vaginal)
- Protection (condoms, when, how often; status discussions)
- Past STI Hx (pathogen, location, frequency)
- Pregnancy (desire for it, prevention methods

Some Tips

- Safe patient environment
- Confidentiality
- Be non-judgmental
- Be sensitive, but matter-of fact
- Avoid assumptions

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Counseling: Sexual behavior

- Deemed important by iPrEx participants in US: Nonjudgmental, open ended, data-driven, motivational
- Sexual behavior/HIV risk reduction: Probe for Pt's knowledge of risk, prevention measures:
  - "What's been going on sexually in last X months?"
  - "In the past 12 months, have you had vaginal sex? Anal sex? How many partners"
  - "When you have anal sex, how much of the time are you the bottom, the top?"
  - "What are the elements of your HIV prevention plan and how does PrEP fit into them?"
  - "Tell me about any exposures you might have had in the last week"→ASSESS FOR PEP!!!!!

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Eligibility assessment: MSM

BOX B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM[2]

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

CDC: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline

Eligibility Assessment: Heterosexual

Box B2: Recommended Indications for PrEP Use by Heterosexually Active Men and Women

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner

CDC: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline

CDC recommendations for HIV testing

- Document nonreactive antibody test within ONE week prior to starting/restarting PrEP, and every 3 months on PrEP
  - Lab-based antibody (EIA) on blood *or*
  - Rapid FDA approved fingerstick antibody
  - NOT oral rapid antibody test
  - NOT patient self-reported test
  - NOT anonymous test
- Standard confirmatory testing, CD4, viral load if antibody-reactive
- If AHI suspect, delay PrEP, send RNA

USPHS: Preexposure Prophylaxis For the Prevention of HIV Infection in the United States-2014: A Clinical Practice Guideline

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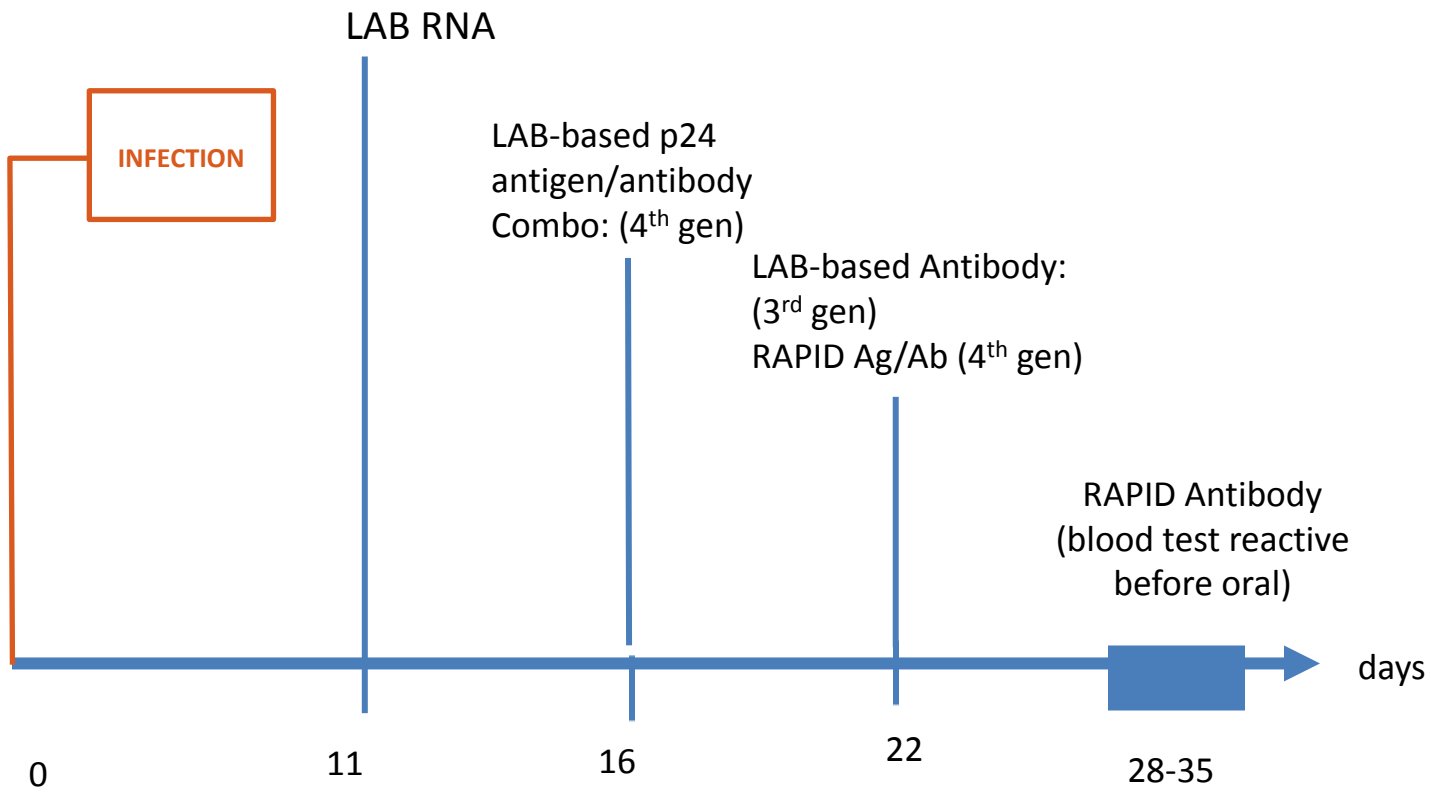
Approximate Sensitivity of HIV Tests for Acute/Recent Infection



Acute Symptoms (+/-)

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Screening for Acute HIV Infection

Table 7: Clinical Signs and Symptoms of Acute (Primary) HIV Infection[65]

Features (%)	Overall (n = 375)	Sex		Route of transmission	
		Male (n = 355)	Female (n = 23)	Sexual (n = 324)	Injection Drug Use (n = 34)
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

IF YOU SUSPECT AHI, REFER FOR IMMEDIATE EVALUATION, RNA TESTING!!!!

CDC: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline

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STI's, screening

- STI incidence on PrEP: data just emerging
  - Preliminary data suggest considerable incidence, but not significantly different from baseline (PROUD, IPERGAY
- Screen q3m
- Use NAAT testing for gonorrhea (GC and Chlamydia (CT)
- CRUCIAL to screen for pharyngeal, rectal GC, CT (usually asymptomatic), as well as urethral, cervicovaginal
- Serology for syphilis

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Self Advocacy

- The person seeking PrEP may have to teach the provider about the realities of sex and sexual health and gain comfort talking about their HIV risks
- Objective measures, such as those provided in the CDC guidelines and NYS guidelines are a great tool to bring the provider

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Insurance Questions

- What are my co-payments or deductibles for visits, labs and medications?
- Are there prior-authorization rules in place to restrict use?
  - What are the rules?
  - What will my doctor need to provide to my insurance company?
  - How can I appeal if I am denied?

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Gilead MAP

- GILEAD Medication Assistance Program (MAP)
  - Income below 500% of the FPL. No other sources for health insurance or coverage
  - Have a prescription for PrEP. Reevaluated for coverage on a regular basis
  - U.S. residency proof is required, but not immigration legal status.
  - Income verified
  - Drugs shipped to provider's office—may take two weeks
  - Contact: 1-855-330-5479

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Gilead Co-pay

- $300 per month
- Deductible and co-insurance coverage is limited to $300 per month
- People must have private insurance
- This program does not cover individuals with Medicaid, but it does cover those with Medicare
- No income requirement
- Issues a co-pay card for use at pharmacies
- Works with most pharmacies, but reimburses when pharmacies don't accept the card. Some mail-order pharmacies also don't accept co-pay cards
- www.gileadcopay.com or 1-877-505-6986

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PAN Co-pay

- $4,000 per year – may reapply, but program funding will dictate response
- Does cover deductibles and co-insurance and is designed for those who's out-of-pocket costs are not fully covered by the Gilead program
- Income below 500% of FPL
- People must have private insurance
- This program does not cover individuals with Medicaid or Medicare
- Most pharmacies should be able to bill PAN directly
- www.panfoundation.org/fundingapplication/welcome.php or 1-866-316-PANF

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Resources

- Project Inform HIV Infoline: http://www.projectinform.org/helplines/infoline/
- PrEP Facts Facebook Page
- Fair Pricing Coalition PEP and PrEP co-pay and MAP resource: www.fairpricingcoalition.org/projects

Supporting providers and clients: Billing issues

- Covering labs
  - Some plans only cover one HIV test/year
  - Gilead has a program to cover HIV testing

- Billing for an office visit (initial and subsequent)
  - Visit Type (CPT): Preventive Counseling (99401-99404)
    - 99401: 15 minutes
    - 99402: 30 minutes
    - 99403: 45 minutes
    - 99404: 60 minutes
  - Diagnosis (ICD9): use both
    - V69.2: High Risk Sexual Behavior
    - V01.79: "contact with or exposure to other viral diseases"

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ACA issues

- SFDPH/CA Office of AIDS analysis:
  - FTC/TDF classified as a specialty drug
  - Avoid Bronze plans (lower premiums but higher drug costs)
  - Silver plans + drug assistance programs offer lower drug costs; additional savings from federal premium reimbursement if patient qualifies

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Counseling: Medication issues

- Adherence
  - Ask about pill taking several ways
  - What makes it easier to take your pills daily?
  - What makes it more difficult?
  - What could you do to make it easier?
  - Tools: alarms, pillboxes, combining PrEP with other daily meds or activities
- Discussion of most common side effects, mitigation strategies
  - With/without food, bedtime dosing, waiting it out
  - Anticipatory guidance

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Toxicity Monitoring for FTC/TDF PrEP

- Rule out active HBV before starting
  - Risk of hepatitis rebound if FTC/TDF stopped

- In HIV(+)s, TDF renal toxicity can occur at any time after starting: usually incremental rise, followed by incremental fall after drug d/c'd
  - More likely if pre-existing renal disease (in HIV+ patients)
  - RARE in PrEP RCTs
  - Usually NOT clinically significant, rarely requires drug interruption

- CDC/FDA: Serum creatinine at baseline and q3-6months
  - Goal is CrCl>60 mL/min
  - Watch the trend
  - Confirmed CrCl<60 at baseline a contraindication for PrEP

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Conclusions

- FTC/TDF PrEP can be highly protective against HIV infection, depending on adherence
- Safe, well tolerated
- Resistance rare in RCTs with monthly monitoring; essential to rule out acute HIV infection before starting
- Emerging data on STI's, condom use
- Brief, nonjudgmental adherence and behavioral counseling important
- Need to increase awareness among potential clients, providers; solve financing issues
- "Real world" data from demonstration projects awaited

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PrEP Research Agenda

- New oral agents
  - HPTN 069 (NEXT-PrEP)
    - Maraviroc + FTC
    - Maraviroc + TDF
    - Maraviroc alone
    - Truvada alone
- Alternate dosing
  - ADAPT
    - Daily dosing
    - Time-driven (twice weekly + dose post-exposure)
    - Event-driven (before and after exposure)
  - IPERGAY
    - Before and after sex
- Other routes of delivery
  - Vaginal microbicides, rings
  - Rectal microbicides
  - Long acting IM
    - -Rilpivirine
    - -GSK 1265744
- More data from Trans people
- How to improve adherence?
  - "real time" drug levels?
- Provider capacitation
  - Public Health Detailing
  - Clinical Mentoring
  - Distance learning
- Financing

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Thanks!

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Client Scenarios

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Scenario #1

- 40 year old Alaska Native HIV+ homeless female is well controlled on ARV and has maintained viral suppression since starting meds upon diagnosis.

- She has tested positive for Gonorrhea 4 times in the two years since her diagnosis (both vaginally and orally). She has multiple partners and often trades sex for alcohol, drugs, transportation or other needs. She is involved in a steady relationship with a male partner.

- Her HIV medical provider prescribed PrEP for him, but follow up has been difficult. He has lost his backpack containing the medications multiple times and often does not follow through on appointments for follow up testing. Because they are both beneficiaries of the tribal health system, the medication is provided at no direct cost to him.

- What are the key issues at play here, and how might you address them with the male partner, the female partner, or both?

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Scenario #2

- A 36 year old HIV negative MSM presents at an outreach testing event for STD/HIV testing services.

- He is currently on PEP for an exposure to HIV prescribed by a family physician. He is requesting information about PrEP to give to his doctor.

- The PEP regimen is almost complete, but he is concerned about potential exposures he has had since getting on PEP and is afraid to discontinue it after the original 30 day course.

- He wants to know the best way to transition from PEP to PrEP without losing the protective benefits of PEP in between.

- His physician is open to prescribing PrEP as an alternative but is unfamiliar with the clinical considerations and prescribing recommendations. He has good private insurance, and is not particularly concerned about the cost.

- What are the key issues at play here, and how might you help him address them with his provider?

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Scenario #3

- A 23 year old HIV+ MSM presents to his HIV provider with urethral discharge and dysuria x 3 days). His urine is tested for gonorrhea and chlamydia and he is presumptively treated for both. He is positive for gonorrhea.
- His viral load is on ARV, but has had urethral gonorrhea twice and syphilis in the last 2 years. Being virally suppressed makes him more willing to engage in unprotected sex as he believes his risk of HIV transmission is low. He has a steady partner, but also has sex with partners he meets on Grindr.
- A DIS worker arranged for the partner to get tested for HIV and STIs, and STI treatment. The partner was negative for HIV but was positive for gonorrhea and chlamydia rectally. The DIS discussed risk reduction strategies with him, but because the index patient 's VL is undetectable the partner was told he does not need to be concerned about contracting HIV.
- The DIS educated the partner about PrEP and recommended that he discuss it with his partner (the index patient) and possibly his HIV provider. The partner is uninsured, so cost of the medication will be a consideration.

- How would you counsel the partner about HIV and STI risk? Paying for PrEP? Finding a PrEP provider? Talking to a provider about his risk?

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Scenario #4

- A 28 year old male MSM who identifies as gay living in Anchorage presents at a community based organization for routine HIV screening. He just moved to Alaska from the lower 48 six months ago, and gets tested for HIV regularly, about every six months. This is his first test in Alaska.

- He was in a steady relationship for 3 years that ended when he moved to Alaska. Since the end of his steady relationship, he admits he has gone a little "wild" having sex with multiple partners, and admits that he has been with 10-15 partners since he arrived in Alaska. He meets his partners through apps such as Grindr and Scruff since he is new to town.

- He had Gonorrhea a few months ago, but isn't that worried about getting HIV. He says he "sometimes" uses condoms and always asks his partners their HIV status.

- He has insurance but with a very high deductible and co-pay, and is very concerned about the cost of PrEP or any other risk reduction strategies.

- How would you counsel him about his HIV risk? About paying for PrEP?

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Scenario #5

- A 45 year old MSM who is non-gay identified presents at a public health clinic to be tested for STD/HIV.

- He is meeting sex partners online, primarily through Craigslist, has tested positive for rectal and oral Gonorrhea and Chlamydia multiple times over the previous year, and recently tested positive for syphilis.

- He does not use condoms, and states that he does not intend to use them in the future.

- He is interested in PrEP and has good insurance coverage, but does not want to schedule any medical appointments which will bill his insurance, because he worries about family members “snooping”.

- What advice could you give him about talking through the insurance issues with his provider?

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Scenario #6

- A 28 year old HIV positive male who is in a long-term, monogamous relationship with an HIV negative woman presents at his medical case management appointment at a local community based organization.

- He and his partner consistently and correctly use condoms, but would like to start planning for a family. He has read about PrEP online, and asks his case manager how he can bring the topic up with his doctor at his next HIV medical appointment and what steps he and his partner can begin taking now to ensure she is a good candidate for PrEP.

- He is currently insured through ADAP/Ryan White, and his partner has insurance coverage through her job, although “it is not great”. They anticipate that she would apply for Medicaid/Denali Kid Care once she becomes pregnant.

- What are the key issues at play here for each of them, and how might you address these?

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