MAT TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Medication Assisted Treatment

Hepatitis C and HIV and Opioid Use Disorder

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Dr. Edelman, Disclosures

- Has no financial relationships with an ACCME defined commercial interest.

The contents of this activity may include discussion of off label or investigative drug uses. The faculty is aware that is their responsibility to disclose this information.

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- Served as a consultant and Key Opinion Leader for Cardiocore, INC.

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Target Audience

- The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

Educational Objectives

- At the conclusion of this activity participants should, among patients with opioid use disorder,
  - Be aware of screening and testing strategies for HCV and HIV;
  - Discuss the natural history and transmission risk of HCV and HIV;
  - Understand HCV and HIV prevention strategies;
  - Review current treatment approaches for HCV and HIV and recognize important treatment considerations

Outline

- For both HCV and HIV:
  - Review natural history and transmission risk
  - Discuss screening and testing
  - Discuss prevention
- In patients on opioid agonist treatment discuss the following with regard to HCV and HIV:
  - Treatment considerations and options
  - Drug-drug interactions
  - Considerations for the co-infected patient

Case 1: J.O.

- J. O. is a 26 year old man with history of opioid use disorder requesting treatment.
- Started using oxycodone/acetaminophen intranasally up to 180 mg daily at age 18 at
- Age 22 switched to heroin use intranasally daily and at age of 24 began using up to 5-10 bags of heroin IV daily.
- Has multiple female sexual partners and rarely uses barrier protection.
- Never been in treatment for opioid use disorder before and is requesting evaluation for buprenorphine treatment.

Next steps for J.O.

- In addition to assessing J.O.'s needs for addiction treatment, what other risk assessments should be performed?

Next steps for J.O.

- In addition to assessing J.O.'s needs for addiction treatment, what other risk assessments should be performed?
  - Provide overview of epidemiology, natural history and transmission risk of HCV and HIV
  - Screening and education for HCV and HIV
  - Discussion of prevention of HCV and HIV

HCV: Epidemiology

- 2.7 million in U.S
- One third of IVDU age 18-30 years
- >70% of IVDU age 30+ years
- ~130-150 million globally
- “Baby boomers” (1945-65) account for 75% of HCV
- Up to 75% of those infected with HCV are unaware
- Leading cause of cirrhosis, hepatocellular cancer, and reason for liver transplantation in the US

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 64 / No. 17
May 8, 2015

TABLE. Sociodemographic characteristics and risk factors for reported acute hepatitis C infection among adolescents and young adults aged <30 years, by urbanicity — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012

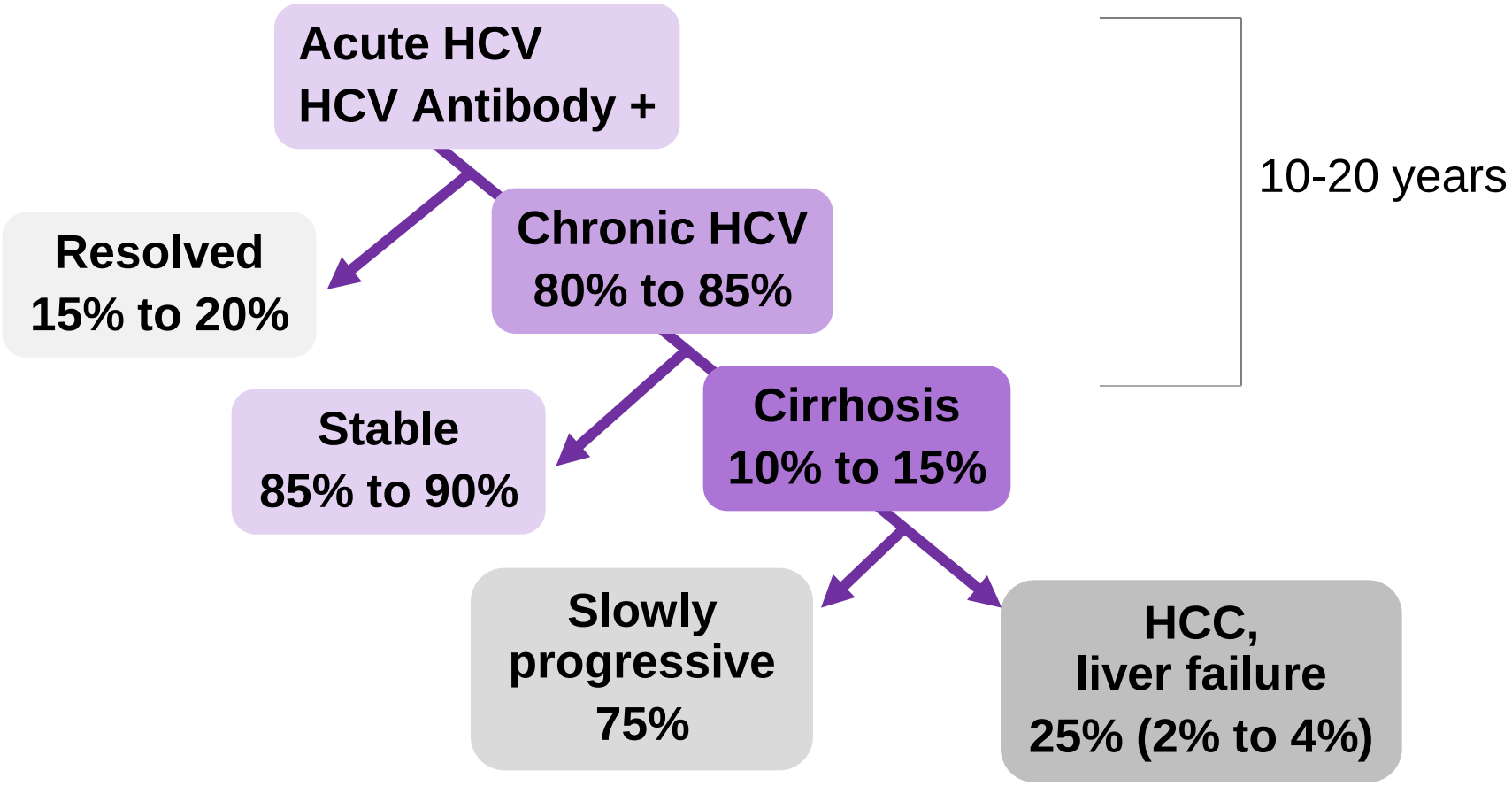
	Urban*		Nonurban†	
Characteristic	No.	(%)	No.	(%)
Median age (yrs)	**25**		**25**	
Sex				
Male	142	(47.2)	157	(49.8)
Female	155	(51.5)	156	(49.5)
Unknown	4	(1.3)	2	(0.6)
Race/Ethnicity				
Black, non-Hispanic	5	(1.7)	0	(0.0)
White, non-Hispanic	249	(82.7)	247	(78.4)
Hispanic	2	(0.7)	3	(1.0)
Other	7	(2.3)	5	(1.6)
Unknown	38	(12.6)	60	(19.0)
Injection drug use reported§	**99**	**(71.7)**	**95**	**(74.8)**
Total	**301**	—	**315**	—

MMWR May 2015

HCV: Risk factors

- Intravenous drug use
- Intranasal drug use
- Multiple sexual partners
- HIV positive, HBV positive
- Hemodialysis patients
- Children born to HCV+ mothers
- Healthcare workers: occupational exposure
- Blood transfusion/organ transplant pre 1992
- Incarcerated persons

HCV: Natural history

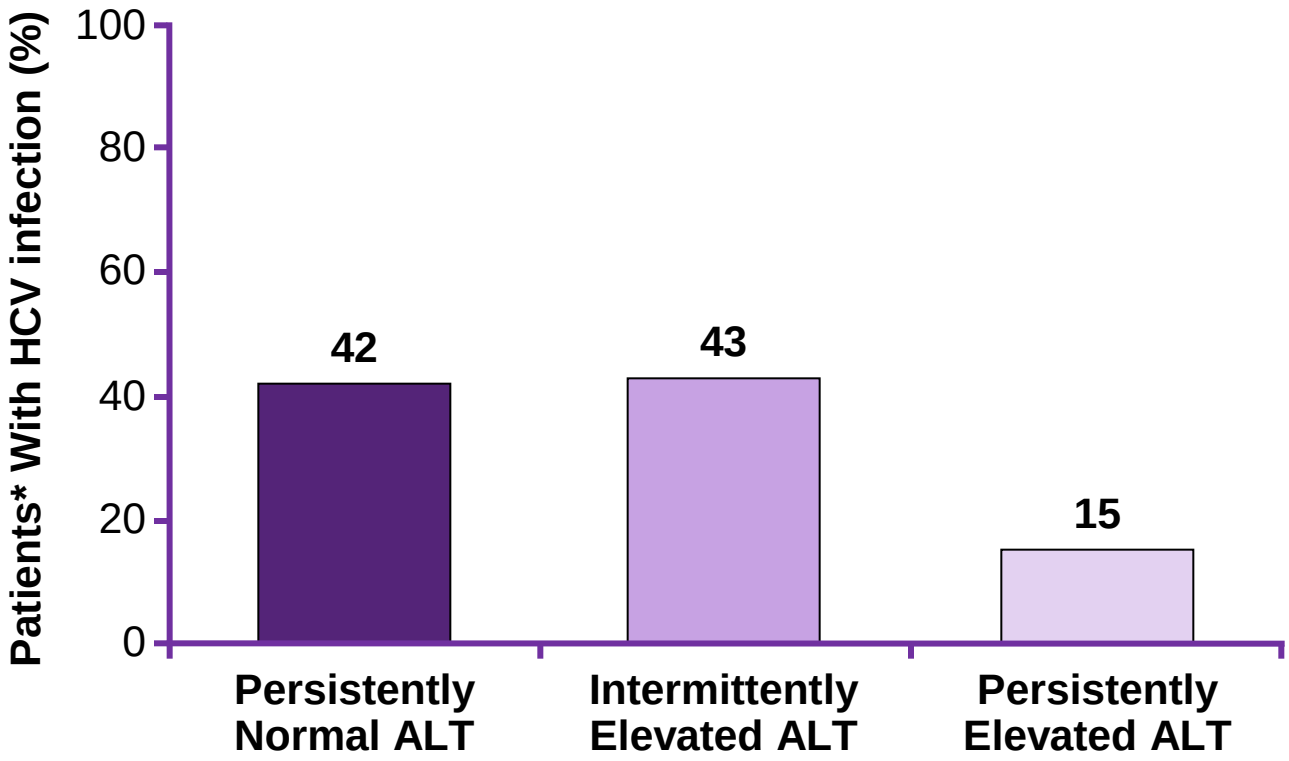


NIH Management of Hepatitis C Consensus Conference Statement. June 10-12, 2002. Available at: http://consensus.nih.gov/2002/2002HepatitisC2002116html.

HCV: Testing

- HCV antibody testing by immunoassay
  - Rapid testing and self-collection kits available
  - Recombinant immunoassay (RIBA) no longer available in US
- If positive→
  - HCV Viral load qualitative or
  - HCV Viral load quantitative + HCV genotype

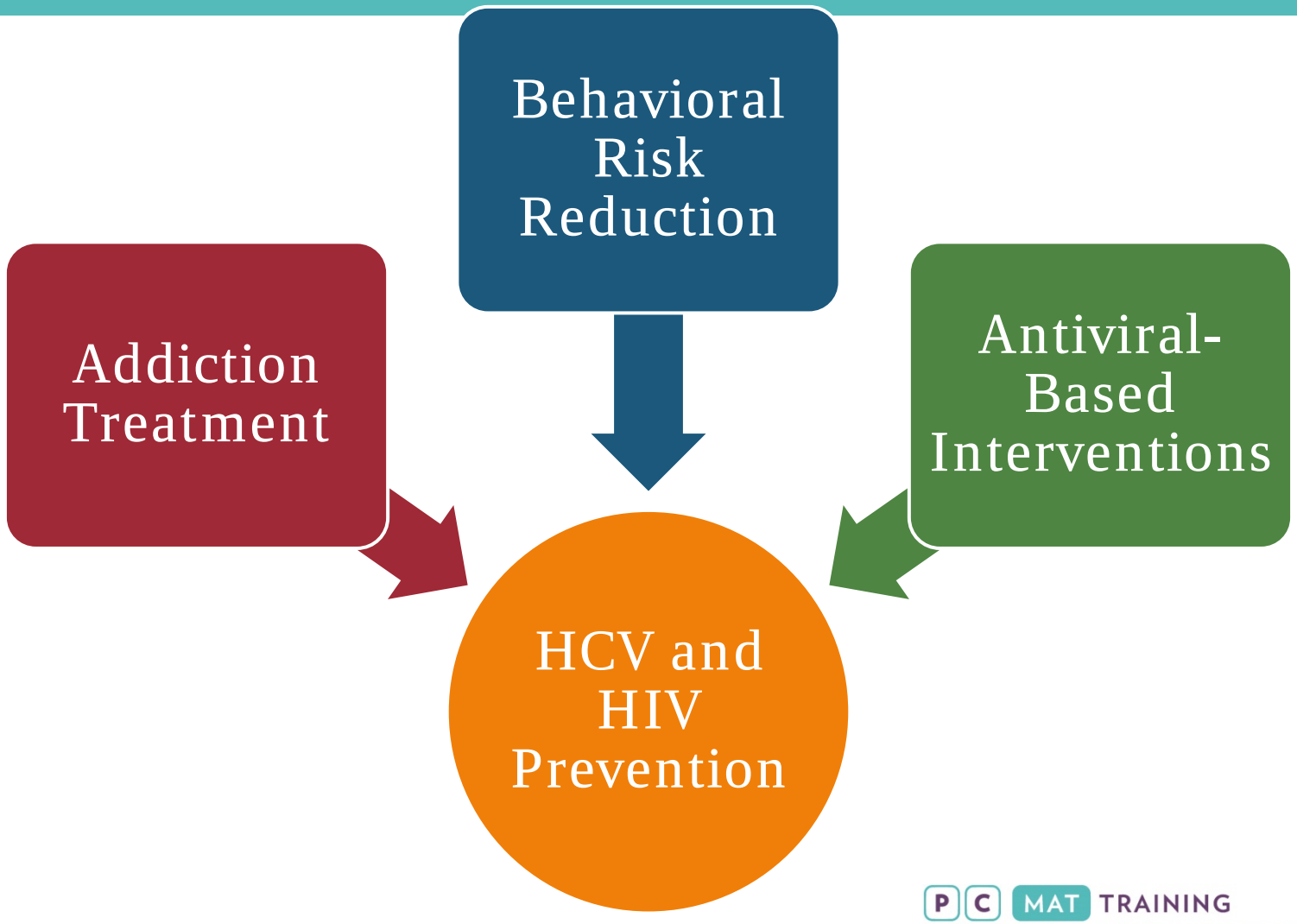
Liver Function Tests in HCV



*Patients with ≥ 4 serum ALT level measurements during 25 months of follow-up (n = 1042).

Inglesby TV, et al. *Hepatology*. 1999;29:590-596.

HCV and HIV Prevention Strategies



Adapted from: Coffin, PO et al. Novel interventions to prevent HIV and HCV in persons who inject drugs. 2015. *Current HIV/AIDS reports.*

HCV: Opioid Agonist Therapy as Prevention

Characteristic	AHR of incident HCV infection	95% CI	*P*
Drug treatment, past 3 months			
None	Referent	Referent	
Non-OAT	0.71	0.41, 1.20	0.20
OAT detox	1.39	0.73, 2.67	0.32
OAT maintenance	0.39	0.18, 0.87	0.02

Tsui JI et al. Association of OAT with lower incidence of HCV in young Adult injectors. *JAMA Internal Medicine.* 2014.

HIV: Prevalence among IDU

TABLE 1. Number and percentage of all participants* and participants who did not report a previous positive HIV test result† who tested positive for HIV infection, by selected characteristics — National HIV Behavioral Surveillance System: Injecting Drug Users, 20 U.S. cities, 2009

	All participants			Participants who did not report a previous positive HIV test result		
		HIV infection			HIV infection	
Characteristic	Total no. tested	No.	(%)	Total no. tested	No.	(%)
Sex						
Male	7,298	652	(9)	6,938	292	(4)
Female	2,792	254	(9)	2,643	105	(4)
Race/Ethnicity						
American Indian/Alaska Native	92	6	—§	87	—	—
Asian/Native Hawaiian/Other Pacific Islander	40	—	—	39	—	—
Black	4,687	501	(11)	4,400	214	(5)
Hispanic/Latino¶	2,173	211	(10)	2,077	115	(6)
White	2,762	164	(6)	2,659	61	(2)
Multiple races	321	22	(7)	305	6	(2)
Age group (yrs)						
18–29	1,010	41	(4)	990	21	(2)
30–39	1,813	154	(8)	1,742	83	(5)
40–49	3,143	343	(11)	2,944	144	(5)
50–59	3,471	328	(9)	3,281	138	(4)
≥60	653	40	(6)	624	11	(2)

Broz et al. *MMWR* 2014

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Injection and Risk Behaviors among IDU, past 12 months

- Drugs injected:
  - Heroin 90%
  - Speedball 58%
  - Cocaine or crack 49%
- Receptive sharing of syringes or works:
  - Syringes 35%
  - Other injection equipment (i.e. cookers, cotton, water) 58%
  - Syringes to divide drugs 35%
- Non-injection drug use: 74%

Broz et al. *MMWR* 2014

Sexual Risk Behaviors among IDU, past 12 months

- Unprotected heterosexual sex:
  - Vaginal sex:
    - 70% men
    - 73% women
  - Anal sex:
    - 25% men
    - 21% women

- Unsafe heterosexual sex and receptive sharing of syringes:
  - 41% unprotected vaginal sex
  - 53% unprotected anal sex

Broz et al. *MMWR* 2014

HIV Risk associated with Behavior

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act[a]

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,000[b]
Needle-sharing during injection drug use	67[c]
Percutaneous (needle-stick)	30[d]
Sexual	
Receptive anal intercourse	50[e,f]
Receptive penile-vaginal intercourse	10[e,f,g]
Insertive anal intercourse	6.5[e,f]
Insertive penile-vaginal intercourse	5[e,f]
Receptive oral intercourse	low[e,i]
Insertive oral intercourse	low[e,i]
Other[h]	
Biting	negligible[j]
Spitting	negligible
Throwing body fluids (including semen or saliva)	negligible
Sharing sex toys	negligible

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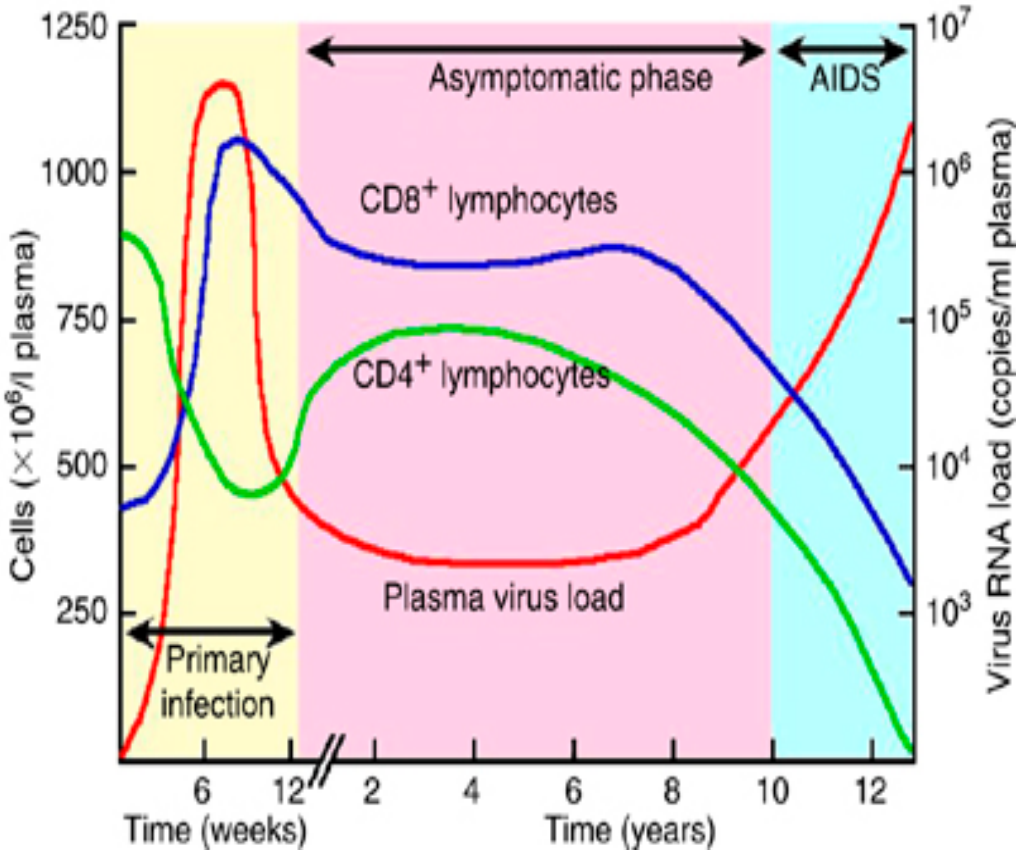
http://www.cdc.gov/hiv/law/pdf/HIVtranmsmision.pdf

HIV: Natural History



Munier 2007 *Immunology and Cell Biology*

HIV: Screening
2006 CDC Guidelines

ONE TIME SCREENING	REPEAT SCREENING AT LEAST ANNUALLY
Age 13-64 years old, unless documented prevalence <0.1%	People with injection drug use and their sex partners
Patients initiating tuberculosis treatment	Persons who exchange sex for money or drugs
Patients seeking treatment for a sexually transmitted infection	Sexual partners of HIV-infected persons
	Men who have sex with men
****Opt-out approach**	Heterosexual individuals who themselves/or partner >1 sex partner since last HIV test

Branson BM et al MMWR 2006

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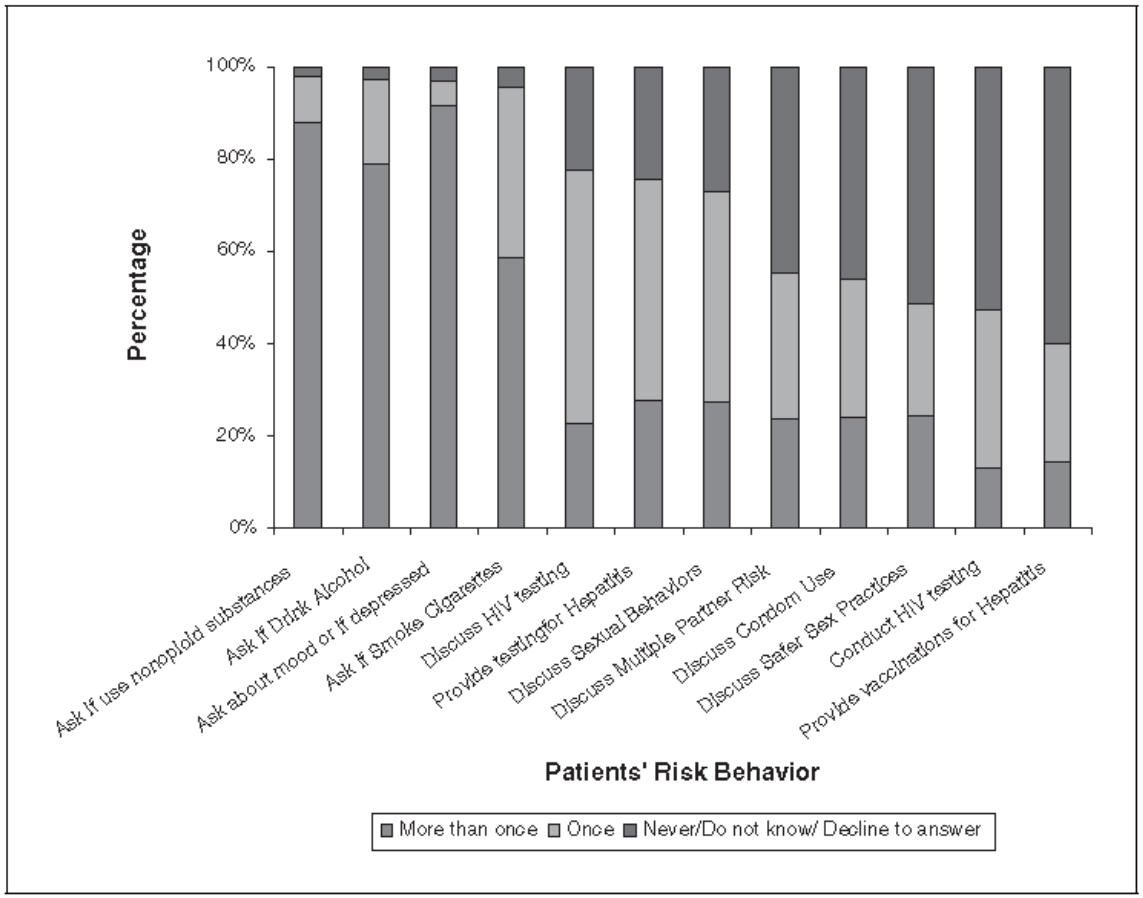
HIV Screening among People with Injection Drug Use

- Despite injection drug use in the past 12 months, 51% had not been tested in the prior year
- Only 11% were tested at drug treatment programs
  - majority in public health clinics or community health centers (14%) or correctional facilities (14%)
- Main reasons for not having had an HIV test
  - 32% fear of finding out they had HIV
  - 25% belief that they were low risk for HIV
  - 11% did not have time
  - 6% did not have money or insurance

Broz et al. *MMWR* 2014

Low HIV Screening by Buprenorphine- Prescribing Physicians



Among 382 providers:

- Alcohol/substance use screening at every visit
- 81% depression screening at every visit
- <25% reporting HIV testing more than once a year; only 14% screened annually

Edelman et al *J Add Med* 2012

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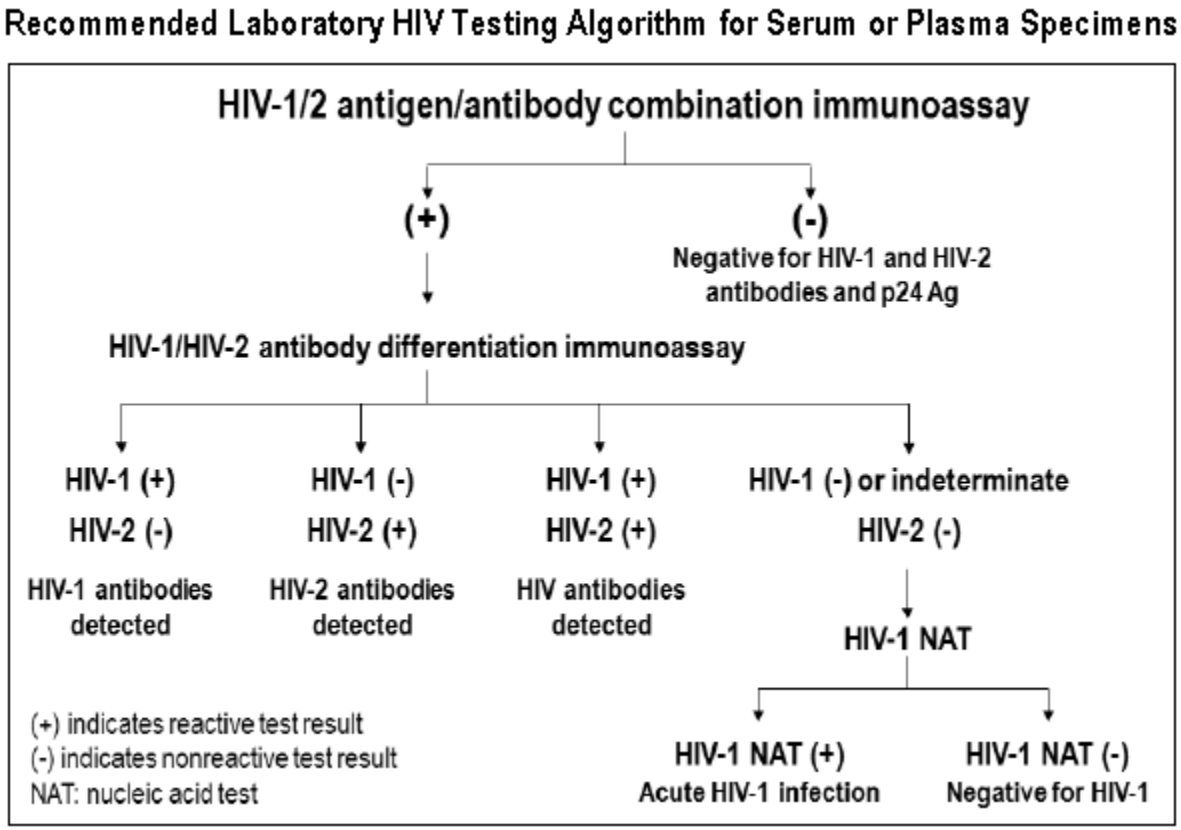
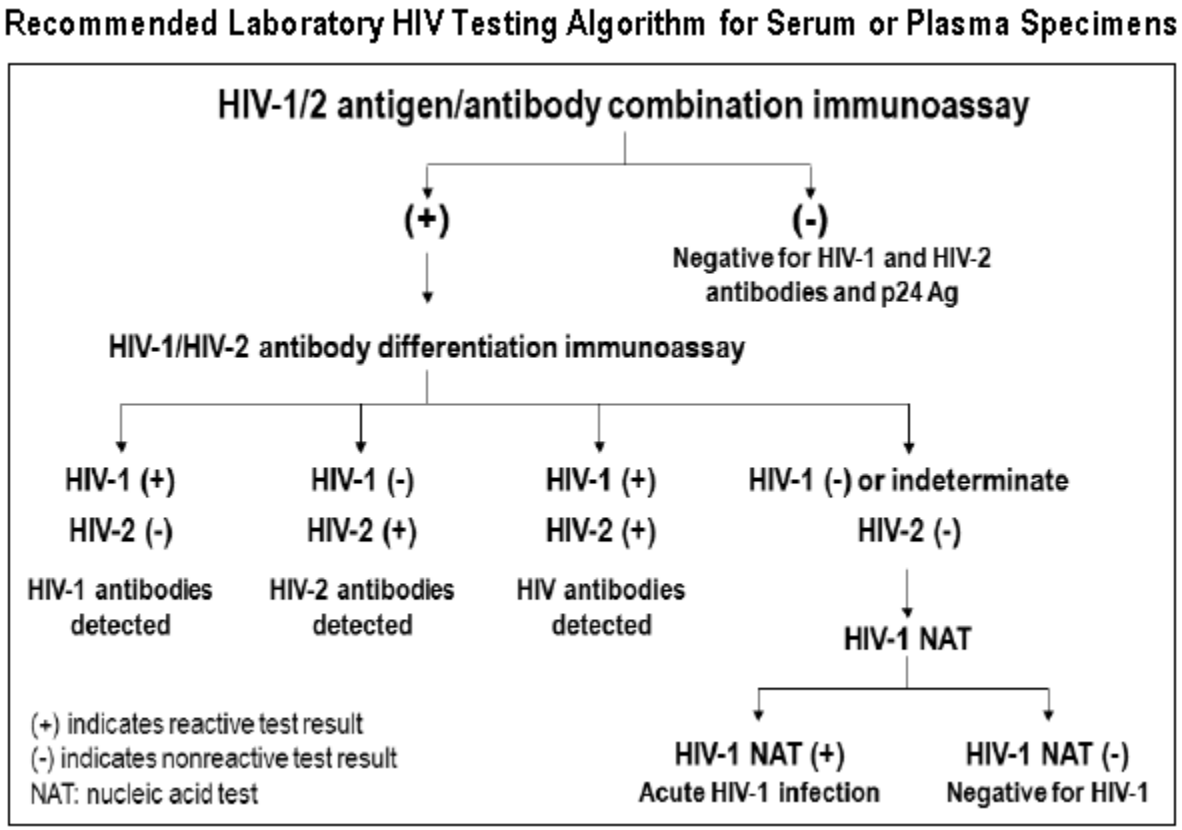
HIV: Screening Algorithm



http://stacks.cdc.gov/view/cdc/23447

HIV: Screening Algorithm



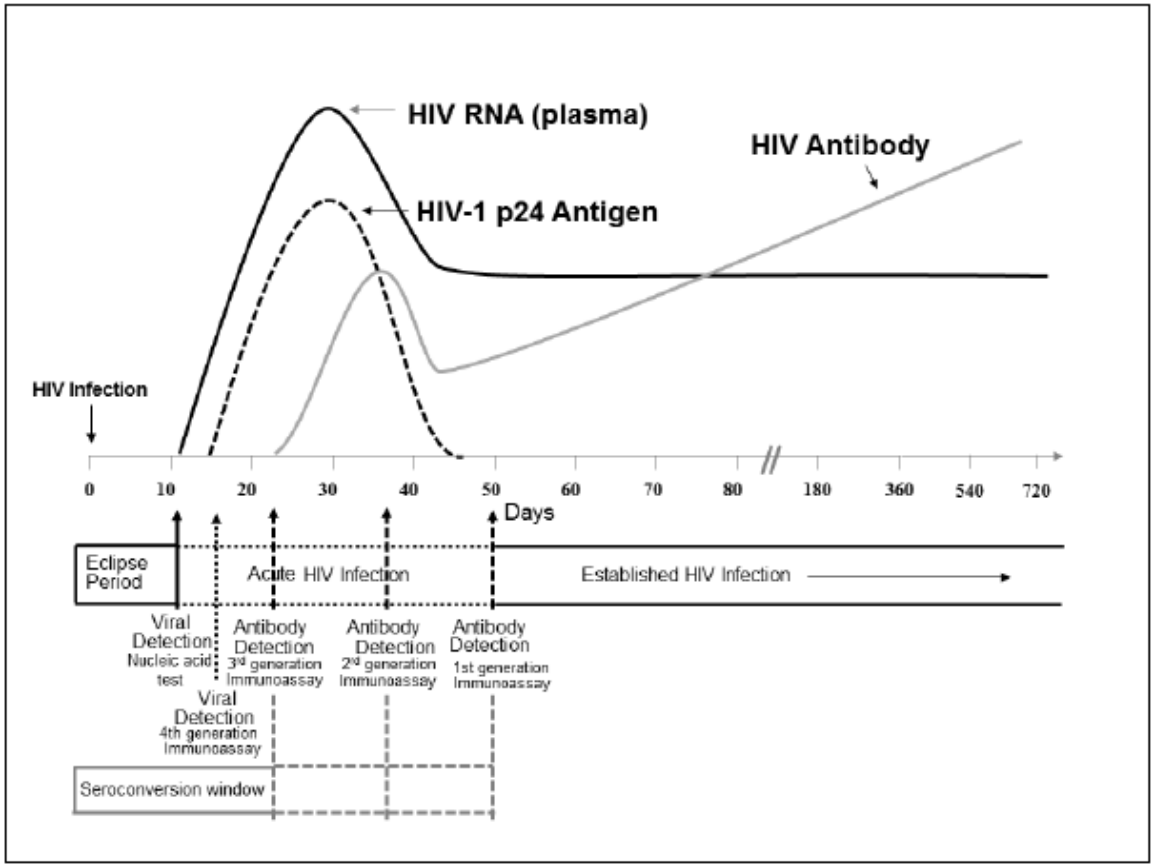
New Strategies:

- No longer rely on Western Blot testing
- 4th generation tests have improved sensitivity and specificity
- But still may miss infection if within 10 days of acquisition

http://stacks.cdc.gov/view/cdc/23447

HIV Screening

Figure 1. Sequence of appearance of laboratory markers for HIV-1 infection



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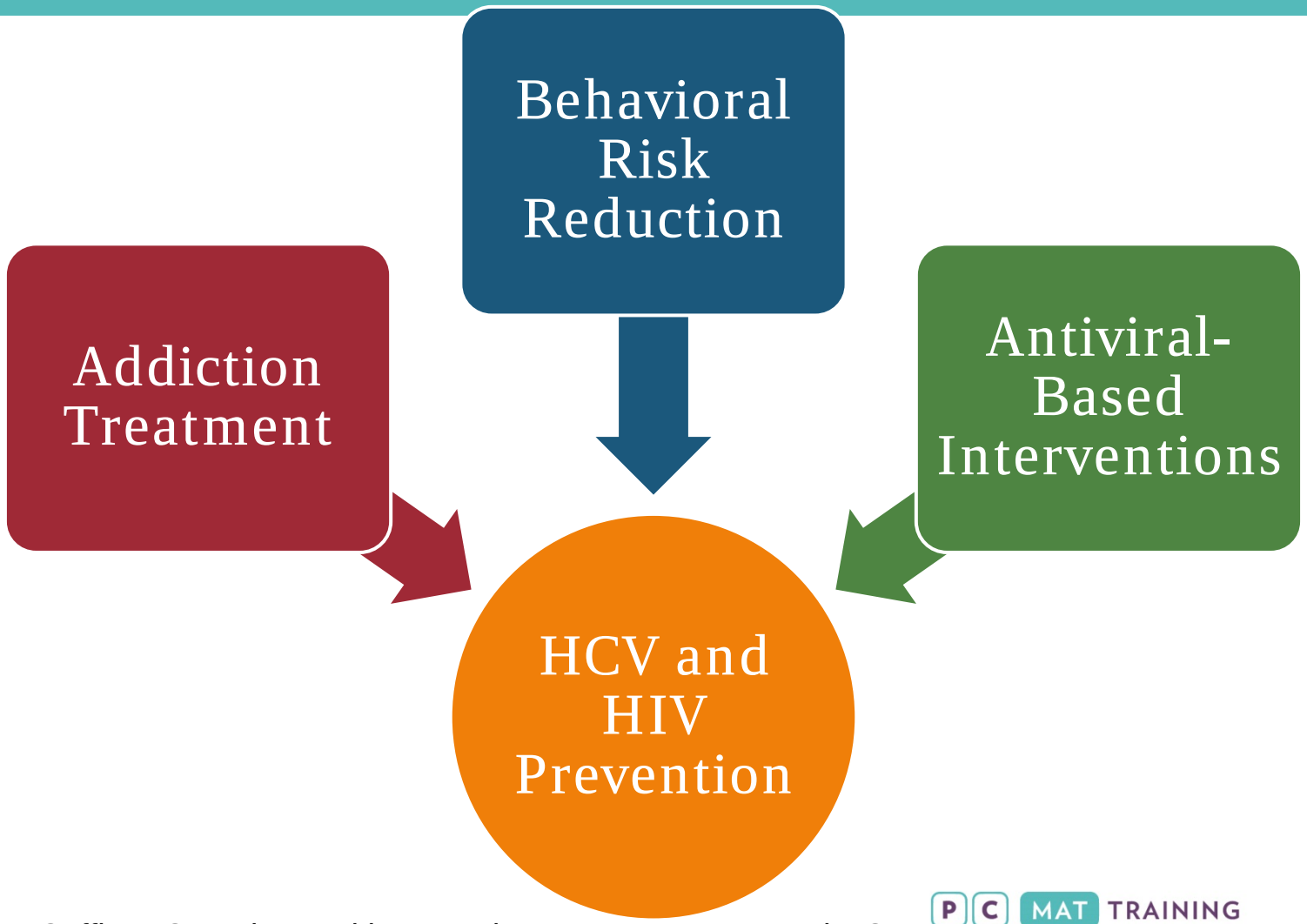
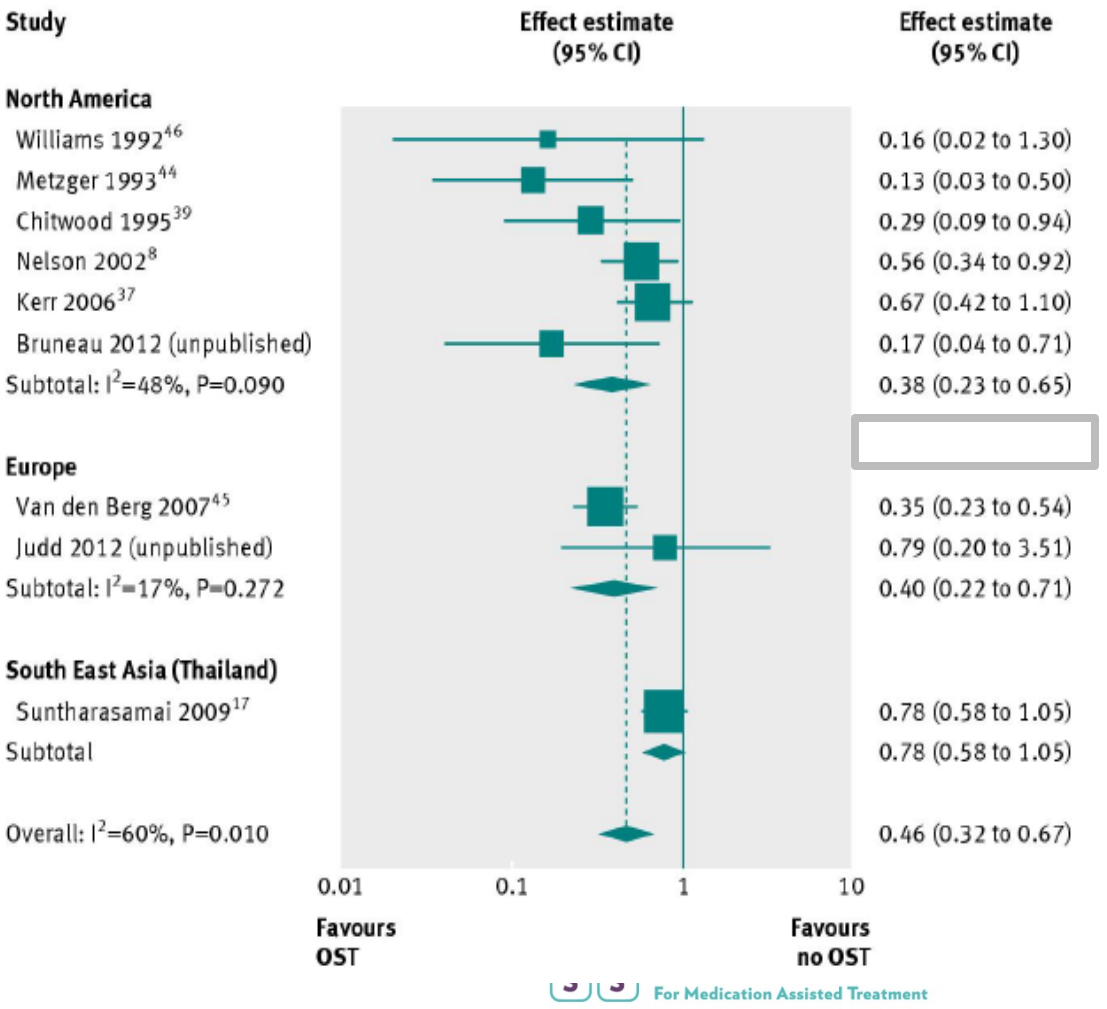
HCV and HIV Prevention Strategies



Adapted from Coffin, PO et al. Novel interventions to prevent HIV and HCV in persons who inject drugs. 2015. *Current HIV/AIDS reports.*

Opioid Agonist Therapy Decreases HIV Incidence

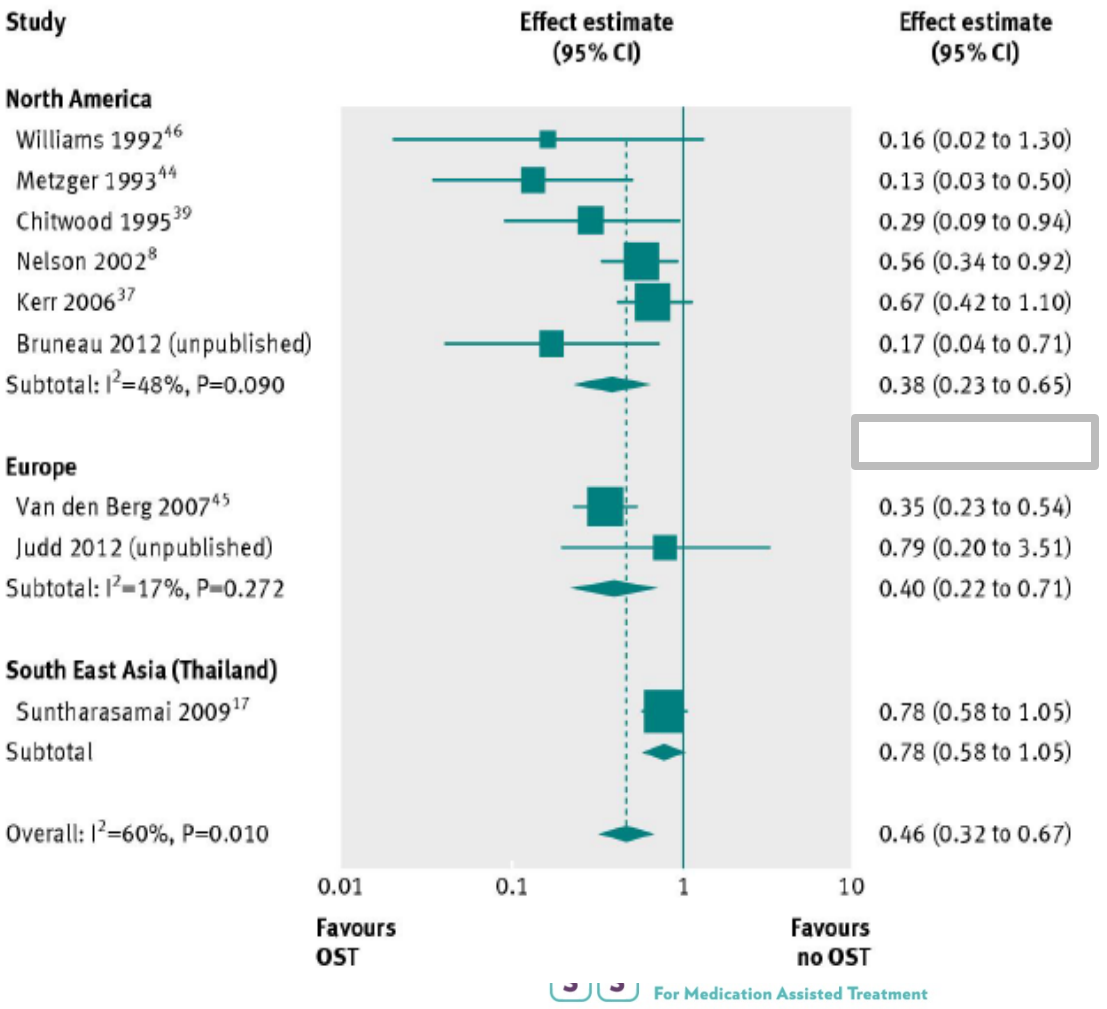
Systematic Review:
- 9 studies
- 23,608 person years
- Methadone only
- Overall effect: 54% reduction in HIV incidence



Gowing et al. *BMJ* 2012

Opioid Agonist Therapy Decreases HIV Incidence

Systematic Review:
- 9 studies
- 23,608 person years
- Methadone only
- Overall effect: 54% reduction in HIV incidence
- North America: 62% reduction in HIV incidence



Gowing et al. *BMJ* 2012

Behavioral Risk Reduction for HIV Prevention

- Needle and Syringe Programs
  - "Sufficient evidence to support effectiveness in reducing injection-related behavior"
  - "Tentative evidence to support effectiveness in preventing HIV"

- Some evidence of other Interventions:
  - Pharmacies, vending machines, supervised drug consumption/injecting facilities
  - Counseling and educational interventions

MacArthur et al. *Int Journ Drug Policy* 2014

Antiviral-based Interventions: Pre-Exposure Prophylaxis for HIV

- Combination of two antiviral medications taken once daily:
  - Emtricitabine/Tenofovir (Truvada)
    - No reported drug-drug interactions with methadone, buprenorphine and naltrexone
- FDA-approved July 2012 for HIV prevention, CDC guidelines 2014
- Bangkok Tenofovir Study, HIV-negative people with injection drug use (n=2,413):
  - HIV incidence decreased by 49%
  - Risk behaviors also decreased

http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf; Choopanya 2013 *Lancet*

Pre-exposure Prophylaxis (PrEP) among People with Opioid Use

- Community-based sample (n=351):
  - February 2013- September 2013
  - Individuals seeking detox
  - Injection drug use in past 30 days

- Major findings:
  - 7% had heard of PrEP
  - 47% willing to take medication to reduce HIV risk
  - 36% very or somewhat unlikely to take PrEP if co-pay

Stein et al *AIDS Behav* 2014

Pre-Exposure Prophylaxis for HIV

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network	HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

STI: sexually transmitted infection

http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

J.O. Continued

- J.O. is stabilized on buprenorphine/naloxone pharmacotherapy with 8mg-2 mg films, 2 films SL daily. He is seen weekly in clinic for the last 14 weeks and the last 10 urines have been (+) for buprenorphine and (-) for all other substances tested. On screening labs, he was found to be positive for HCV-antibody and wants to discuss treatment options.

HCV: When and whom to initiate therapy

Goal of treatment

Reduce all-cause mortality and liver-related health adverse consequences by the achievement of virologic cure as evidenced by an SVR.

Recommendations for when and in whom to initiate treatment

Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies owing to comorbid conditions.

Immediate treatment is assigned the highest priority for those patients with advanced fibrosis, those with compensated cirrhosis, liver transplant recipients, and patients with severe extrahepatic hepatitis C.

Immediate treatment should be prioritized as necessary so that patients at high risk for liver-related complications are given high priority.

Recommendations for pretreatment assessment

An assessment of the degree of hepatic fibrosis, using noninvasive testing or liver biopsy, is recommended.

Recommendation for repeat liver disease assessment

Ongoing assessment of liver disease is recommended for persons in whom therapy is deferred.

www.hcvguidelines.org

HCV: Pre-treatment monitoring

- Further work-up
  - HCV Viral load quantitative with genotype testing
  - CBC, BMP, LFTs, TSH, INR, and urine HCG
  - HIV, Hepatitis A and Hepatitis B screening
  - Assessment of degree of liver fibrosis
    - Non-invasive testing or liver fibrosis
    - If evidence of cirrhosis, screen for varices and HCC
- Review addiction treatment plan for patients with active or recent substance use

HCV Treatment Regimens

GT	Medication	Duration	SVR	Side effects	Interactions
1	Ledipasivr + sofosbuvir	12-24 weeks	>90%	Headache Nausea	PPIs/H2 blockers Crestor Digoxin Oxcarbazepine Modafanil Some HIV/TB medications
2	Sofosbuvir + ribavirin*	12 weeks	92-96%	Headache Nausea Fatigue Depression	Modafanil Oxcerbazepine
3	Daclatasir + Sofosbuvir	24 weeks	92-95%	Headache Nausea Fatigue Depression	Amiodarone HMG-CoA reductase inhibitors Digoxin
4	Ledipasivr + sofosbuvir	24 weeks	>90%	Headache Nausea	As above

*Ribavirin is teratogenic. Must commit birth control for duration of treatment and 6 months after.
www.hcvguidlelines.org

Hot off the presses…

- July 24, 2015: FDA approves new treatment for chronic hepatitis C genotype 3 infection:
  - Daclatasivir + sofosbuvir X 12 weeks
  - SVR 98% treatment naïve, without cirrhosis and 58% of treatment naïve, with cirrhosis
  - Daclatasvir SAE=symptomatic bradycardia
- July 24, 2015: FDA approves new treatment for chronic hepatitis C genotype 4 infection:
  - Ombitasvir, paritaprevir, ritonavir (Technivie) + ribavirin X 12 weeks
  - 100% SVR
  - Increased liver enzymes (esp in patients taking OCP)

J.O. continued

- He successfully completes HCV treatment.
- After three years of consistent engagement in treatment for his opioid use disorder, he is lost to follow-up.
- When he returns to care to reinitiate treatment, he reports that he is injecting 5 bags of heroin daily. He denies any needle sharing, but reports unprotected sex with multiple female partners.
- He is found on routine screening to have established HIV infection.

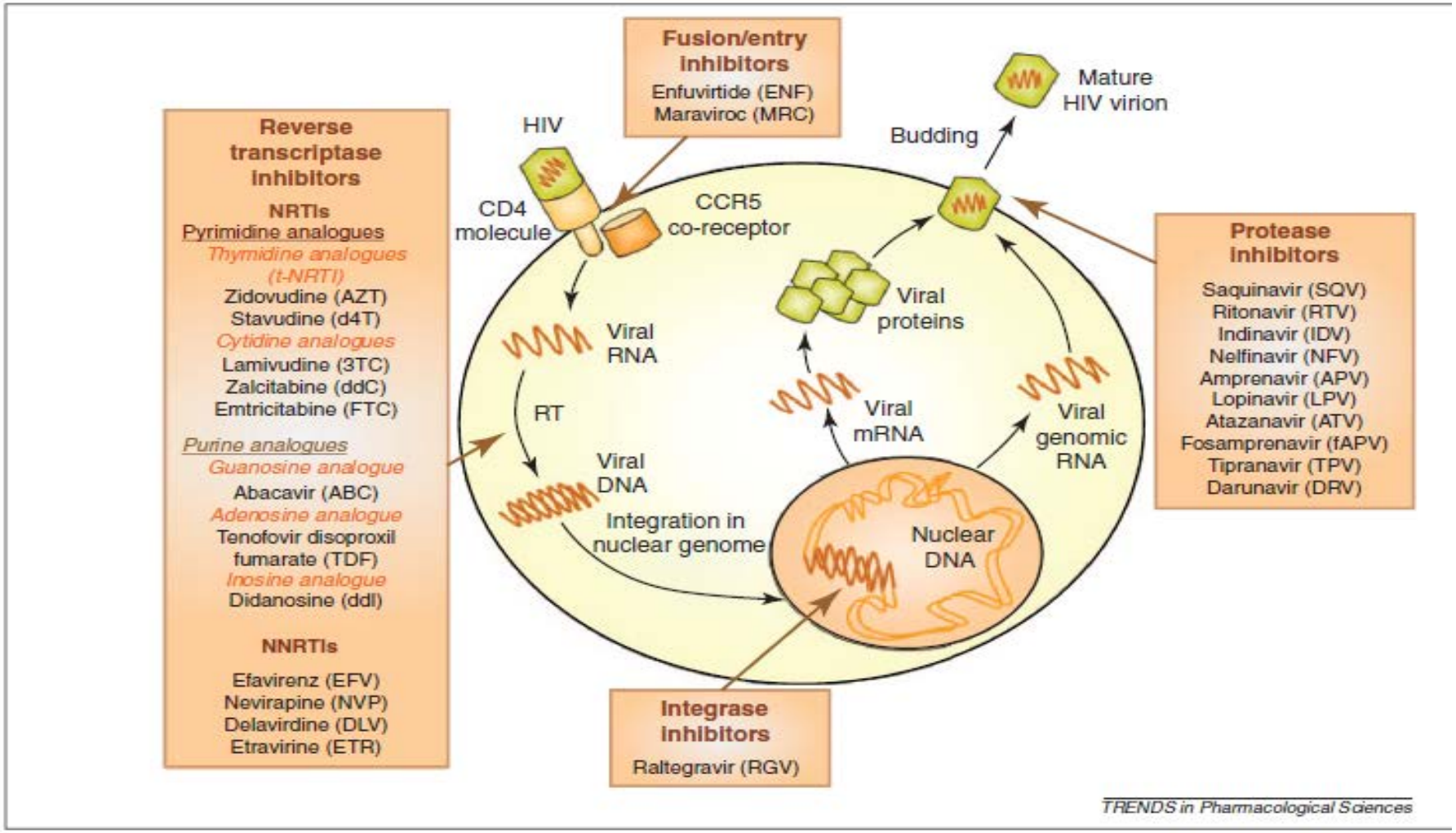
J.O. continued

- What are the current standards for HIV care?
- When is HIV care initiated?
- What are the treatment options for the newly diagnosed patient?
- What are important consideration regarding HIV care among patients with opioid use disorders?

HIV: Considerations for the Newly Diagnosed Patient

ADAPTED FROM THE DHHS HIV/AIDS TREATMENT GUIDELINES	
Goals of Treatment	• Reduce HIV-associated morbidity and prolong duration and quality of survival • Restore and preserve immunologic function • Maximally and durably suppress plasma HIV viral load • Prevent HIV transmission
When to Initiate Treatment	• Recommended for ALL HIV-infected patients regardless of CD4 cell count • Patients starting ART should be willing and able to commit to treatment and understand risks and benefits and importance of adherence; may be deferred on case-by-case basis
Baseline Evaluation	• HIV antibody testing, CD4 T cell count, HIV RNA viral load • Complete blood count, chemistry, transaminase levels, UA • Hepatitis A, B and C serologies • Fasting blood glucose and lipids • HIV genotype at treatment entry regardless of whether starting treatment • Sexually transmitted infections & opportunistic infections screening

HIV Antiretroviral Agents Overview



Apostolova N *Trends in Pharmacological Sciences* 2011

HIV: Recommended Treatment for ART-Naïve Patients

Recommended Agents and Considerations: Consult Guidelines for Details	
Integrase Strand Transfer Inhibitor-Based Regimen	
• Dolutegravir/abacavir/lamivudine	*ONLY if HLA-B*5701 negative
• Dolutegravir + tenofovir/emtrictiabine	
• Elvitegravir/cobicstat/tenofovir/emtricitabine	*ONLY if CrCl > 70 ml/min pre-ART
• Raltegravir + tenofovir/emtricitabine	
Protease Inhibitor-Based Regimen	
• Darunavir/ritonavir + tenofovir/emtricitabine	

DHHS HIV/AIDS Guidelines 2015

Opioid Agonist and Antiviral Treatment Considerations

Medication	Metabolism	Main ART Considerations
Methadone	• Delays gastric emptying • Metabolized by CYP 450 isoenzymes 2B6, 3A4, 2D6	• Efavirenz, nevirapine and all PIs, especially lopinavir/ritonavir decrease methadone levels → opioid withdrawal typically 7 days after co-administration; may need increased methadone dose • Atazanavir levels may be increased → monitor for toxicity
Buprenorphine	• Metabolized by CYP 3A4	• Concern for interaction with atazanavir and decreased levels, do not administer with ritonavir • Monitor for sedation if ritonavir + atazanavir as atazanavir may increase buprenorphine levels • Atazanavir/cobicistat and darunavir/cobicstat effects unknown
Naltexone	• Not metabolized by CYP450 enzymes	• No significant interactions expected or observed

DHSS guidelines 2015

Suboptimal Care for People with IDU along HIV Treatment Cascade

- Approximately 14,500 with injection drug use unaware of their HIV status
  - Testing is not routine in opioid treatment programs and decreasing: 2005 to 2011: 93% → 64%
- Less likely to initiate antiretroviral therapy and quality care
- Less likely to achieve viral suppression
- Less likely to be retained in care

http://www.cdc.gov/hiv/pdf/2011_Monitoring_HIV_Indicators_HSSR_FINAL.pdf

D'Aunno *Health Ser Research* 2014; Hanna DA 2013 *CID*; Korthuis PT 2012 *JAIDS*; Horberg MA 2013 *AIDS Pt Care STDS*; Rebeiro P 2013 *JAIDS*

A Potential Solution: Integrated Addiction and HIV Care

- HRSA-funded Special Project of National Significance: Buprenorphine-HIV Evaluation and Support (BHIVES) Project
  - Integration of buprenorphine into 10 HIV clinics across the United States, 2004-2009, multi-disciplinary team members
- At 12 months, nearly 50% engaged in addiction treatment
- Among those retained in treatment, past 30-day illicit opioid use decreased from 84% to 42%
- Buprenorphine was associated with increased likelihood of initiating and remaining on ART and HIV viral suppression
- Demonstrated feasibility of delivering integrated care as an effective treatment strategy

http://journals.lww.com/jaids/toc/2011/03011

Considerations for HCV/HIV co-infected patients

- Significant drug-drug interactions may occur, therefore, patients should be cared for in collaboration with an HIV practitioner.

- HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications

Summary

- People living with opioid use disorders are at increased risk for HCV and HIV due to needle sharing and sexual risk behaviors
- Comprehensive prevention interventions for HCV and HIV include effective addiction treatment, behavioral risk reduction, and antiviral agents (pre-exposure prophylaxis for HIV, “PrEP”)
- Routine screening is essential for timely diagnosis
- Treatment regimens for both HCV and HIV are highly effective in this population and can be safely used with opioid agonist therapy

Key References

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PCSS-MAT Mentoring Program

- PCSS-MAT Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS-MAT Mentors comprise a national network of trained providers with expertise in **medication-assisted treatment, addictions** and **clinical education**.
- Our 3-tiered mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available, at no cost to providers.

For more information on requesting or becoming a mentor visit:

pcssmat.org/mentoring

PCSS MAT TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Medication Assisted Treatment

MAT TRAINING

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PCSSMAT is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society of Addiction Medicine (ASAM) and Association for Medical Education and Research in Substance Abuse (AMERSA).

For More Information: **www.pcssmat.org**

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