

ROUTINE HIV SCREENING- NECESSARY OR NOT?

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HIV-THE PAST

Since the first case was identified in 1981, acquired immune deficiency syndrome (AIDS) has grown into an epidemic that has taken approximately 500,000 lives in the United States alone

TOM HANKS

DENZEL WASHINGTON

PHILADELPHIA

FROM THE DIRECTOR OF
THE SILENCE OF THE LAMBS

1993 ACADEMY AWARD™
WINNER

BEST ACTOR
TOM HANKS


BEST ORIGINAL SONG
BRUCE SPRINGSTEEN
"STREETS OF PHILADELPHIA"



DVD
VIDEO



CDC HIV TESTING RECOMMENDATIONS 2016

- **RECOMMEND SCREENING ALL PATIENTS AGES 13-64 REGARDLESS OF RISK IN ALL HEALTH CARE SETTINGS WITH A PREVALENCE >0.1%**
 - **VOLUNTARY OPT-OUT TESTING WITHOUT NEED FOR SEPARATE WRITTEN CONSENT**
 - **ELIMINATION OF THE REQUIREMENTS FOR PRETEST COUNSELING IN CONJUNCTION WITH TESTING**
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Total Population
2,680,484

City Population by
Race/Ethnicity

American Indian / Alaska Native
(0.2%)

Asian (5.4%)

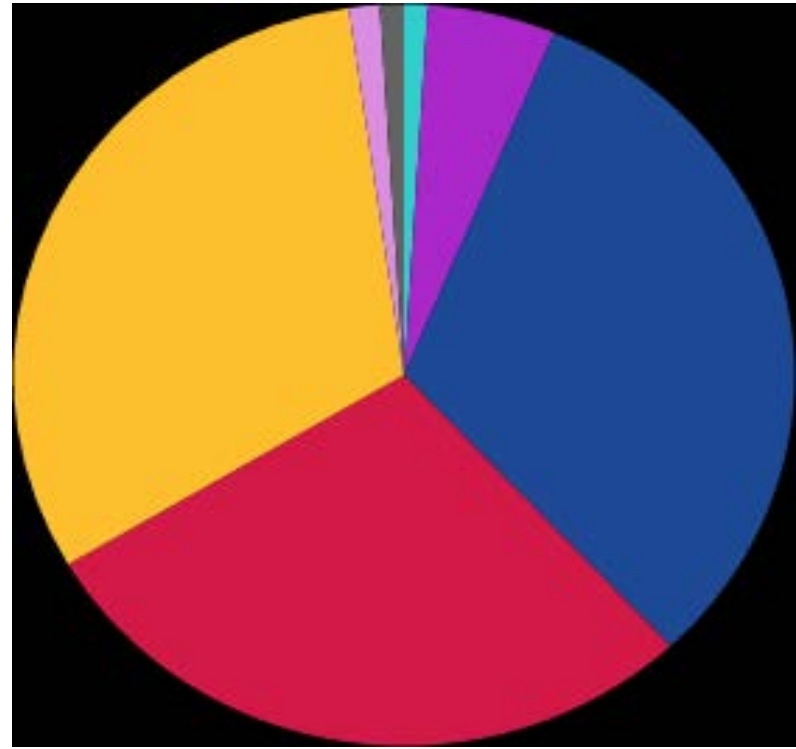
African American (32.3%)

Hispanic / Latino (28.9%)

Caucasian (31.8%)

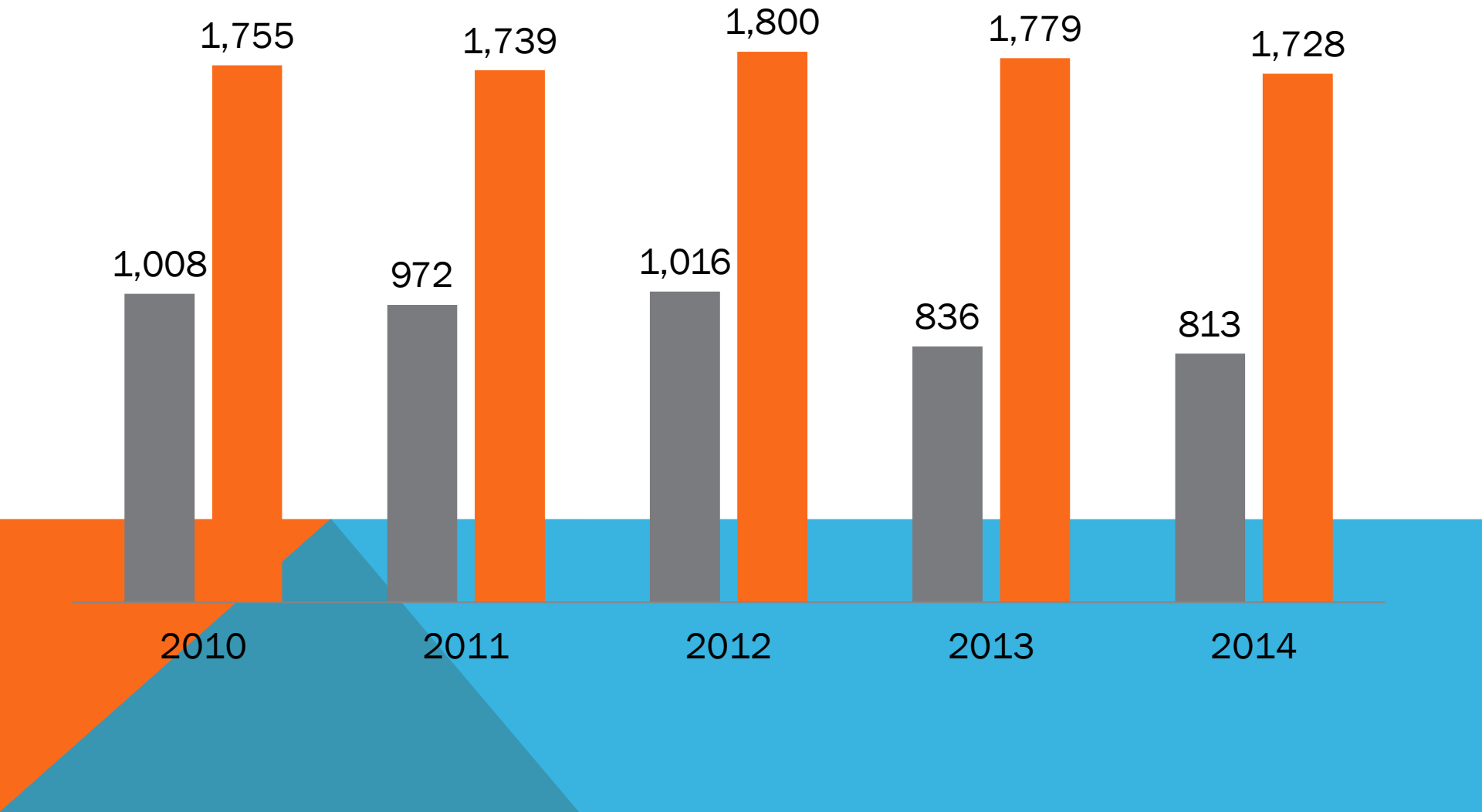
Multiple Race (1.3%)

Other (0.1%)

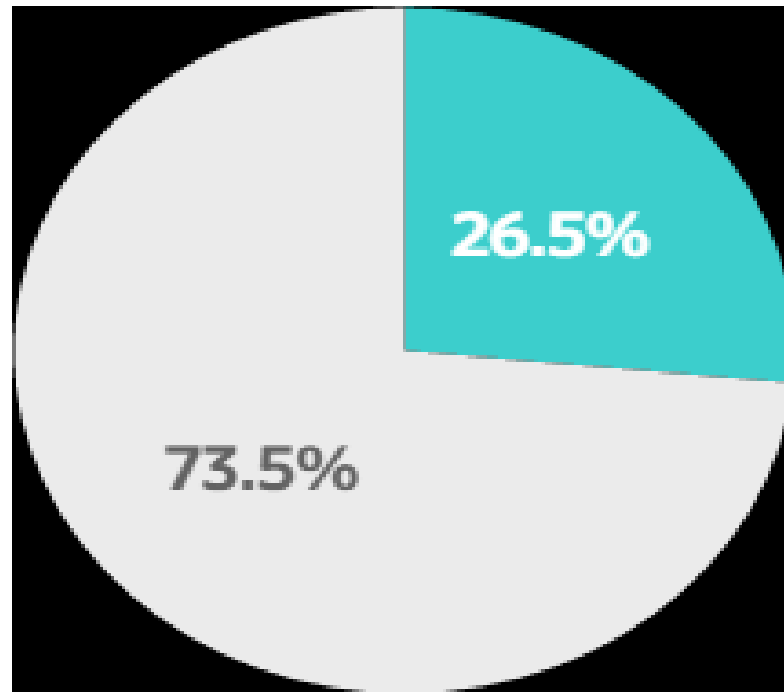


Estimated Number of New HIV Diagnosis , 2010-2014

■ Chicago ■ Illinois



Chicago

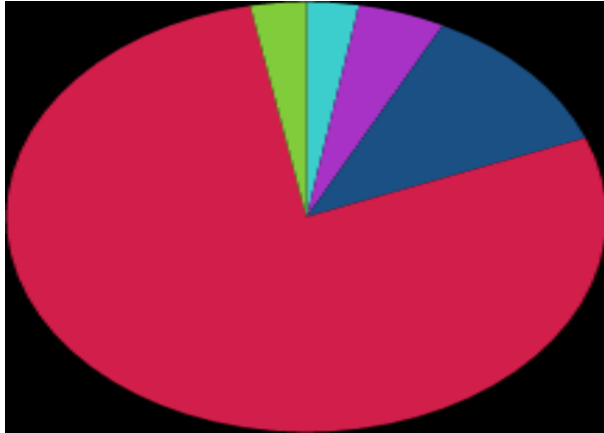


Diagnosed with AIDS
Diagnosed with HIV

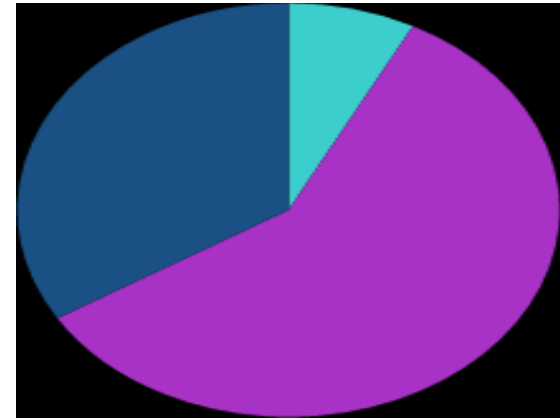
**Estimated Percent of AIDS Diagnoses Within
12 Months of Initial HIV Diagnosis, 2013**

New Diagnoses

Male Transmission Categories



Female Transmission Categories



Male-to-Male Sexual Contact (78.0%)

Heterosexual Contact (58.7%)

5-Year Combined Estimated Percent of New HIV Diagnoses, by Transmission Category, 2010-2014

Sexually Transmitted Diseases, 2013

Chlamydia

Min. Rate Among Cities 293.1

502.4 Chicago

RATE PER 100,000 POPULATION

Gonorrhea

Min. Rate Among Cities 49.9

134.3 Chicago

RATE PER 100,000 POPULATION

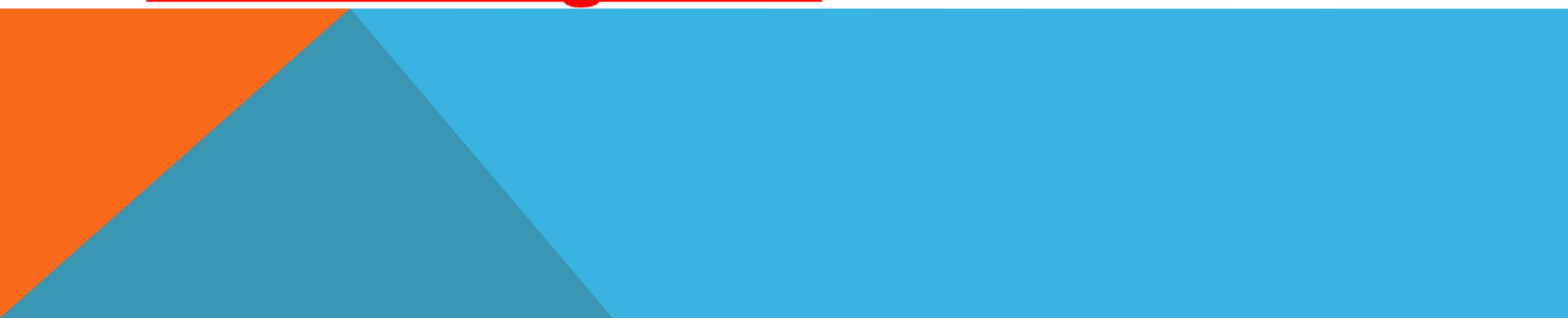
Primary & Secondary Syphilis

Min. Rate Among Cities 1.2

8.0 Chicago

HIV-THE PRESENT

At the end of 2012, an estimated 1.2 million persons aged 13 and older were living with HIV infection in the United States, including 156,300 (12.8%) persons whose infections had not been diagnosed.



EIAs for Diagnosis of HIV Infection

Generation	1st	2nd	3rd	4th	
Antigen					
Sample					
Conjugate					
Signal					
Antigen	Lysate		Recombinant & synthetic		
Specificity	95–98%	>99%	>99.5%	99.5%	
Sensitivity	99%	>99.5%	>99.5%	>99.8%	
Window period	8–10 weeks	4–6 weeks	2–3 weeks	2 weeks	
Immunoglobulin class detection	IgG	IgG	All	All	
Approximate year of first release	1985	1987	1991	1997	
Platforms	Plate assays Particle agglutination	Plate assays Automated generic platforms Particle agglutination Rapid assays	Plate assays Dedicated instruments Rapid assays	Plate assays Dedicated instruments Rapid assays in development	

Diagnosis of HIV Infection

Confirmatory Testing

- Confirmatory Ab testing detects antibodies against specific HIV antigens
 - ~~Western Blot~~
 - Multi-spot
 - Geenius

Geenius HIV-1/HIV-2 Supplemental Assay

Bio-Rad's Geenius™ HIV-1/HIV-2 Supplemental Assay detects and differentiates circulating antibodies to HIV Types 1 and 2

November 24, 2014 – Supplemental Assay can differentiate circulating antibodies to HIV Types 1 and 2 in whole blood, serum and plasma.

Key Benefits:

Minimal training required – small samples of whole blood or plasma into the cassette well, less buffer, shorter wait time between 1st and second well. Results in 20 minutes.

Qualitative interpretation – interpretation of six individual HIV-1 and HIV-2 band results is provided along with a permanent record of the results and an image of the cassette. The data can later be uploaded to a Laboratory Information System.

User-friendly graphical interface – the interface on the notebook computer displays results of the interpretation of the six bands once the cassette is inserted into the reader. A unique 2D barcode on the cassette, read by the Geenius software, positively identifies each cassette, allowing the result and the patient ID to be recorded on a single document.

Early HIV Infection - Definitions

- Acute infection is defined as positive p24 Ag or RNA detection, but negative or indeterminate Ab detection
- Everyone has acute infection at some point
- 25-50 % of patients have symptoms of a viral illness at the time, but usually illness is mild
- 1-2 % of patients will have an acute HIV infection syndrome or primary HIV infection syndrome that is severe enough to bring them into care
 - These individuals have higher viral loads
 - They often have rapid progression of disease

Diagnosis of Acute (Primary) HIV Infection

- May mimic an acute mononucleosis-like or influenza-like illness
- Other typical features include:
 - Fever
 - Pharyngitis
 - Diarrhea
 - Headache
 - Neurological complications
 - Lymphadenopathy
 - Rash
 - Nausea, vomiting
- P24 antigen, HIV RNA (viral load,) or viral culture can detect HIV infection before antibody tests turn positive

- The greatest number of acute infections are seen in the ED
- The majority are young (>24 years of age) African American patients

Significance of Early Infection

Acute and Recent

- Viral load gives an indication of the level of HIV in the body
 - Levels of virus may vary in different tissues and fluids, i.e., brain, genital tract, gut, and breast milk
- Viral load correlates with infectivity
- Patient with acute infection, especially those who are symptomatic, have viral loads that are much higher than in chronically infected patients
- There may be an 8-10X higher risk of transmission during acute infection (peak viral load day 20) compared to chronic infection

STAHRS Testing for Early HIV Infection

Use of a “Detuned” EIA

- A second EIA that can estimate duration of infection
- A negative “detuned” or less-sensitive EIA means the patient was more recently infected
- Can help determine incidence versus prevalence
- This tool was FDA approved
 - Used by Public Health departments
 - Used to determine the incidence of HIV infection in the USA- is 40 % greater than previously estimated (CDC, 2008)
- STAHRS testing may also identify patients with recent infection

TODAY-10 THINGS YOU SHOULD KNOW ABOUT HIV IN 2016

- Expansion of HIV screening has occurred in a dynamic environment of evolving policy recommendations, new scientific discoveries, and improving laboratory methods. Policy developments range from endorsement from federal agencies to modifications of HIV testing laws
- In 2013 the United States Prevention Task Force (USPTF) issued a recommendation for individuals 15-65 years of age be screened for HIV -“A” grade-this determination was important because under the Affordable Care Act, it compelled health insurance providers to cover routine HIV screening without co-payments for members of qualifying health plans. Medicaid & Medicare

- Similarly, the Department of Veterans Affairs revised its policy to recommend routine, rather than risk-based, HIV testing for all veteran's-2015
- Primary scientific developments have expanded our understanding of the need to make a diagnosis and link people to treatment as early as possible. Treatment to Prevention 2013- Treatment to Cure-2015
- Progress towards a new vaccine for HIV 2015, Using lasers to zap the HIV virus
- Male birth-control-2015
- A drug used to treat alcoholism might actually lead to a cure for HIV/AIDS. Basically, disulfiram “wakes up” dormant HIV cells hiding in the bloodstream so that other medicines can eradicate them-2015

- New Laboratory technologies have helped support a transition from screening programs that relied on dedicated testers to perform rapid HIV tests during the care encounter to integration of HIV and other tests through existing laboratory systems using non-dedicated staff members. This promotes larger testing volumes, reduced cost and promotes adoption of HIV screening for HIV and other diseases-2012
- Similar to 4th generation assays; which offer early detection of HIV by detecting HIV antigens and HIV antibodies that are produced by the body to fight the HIV infection. The 5th generation BioPlex HIV Ag-Ab kit provides more information by specifically identifying which individual HIV 1 and HIV 2 marker is positive. 2015- Eliminates the need for reflex testing

“Despite grand efforts to inform about the dangers of HIV, factions of people are embracing the virus. This emerging trend raises some troubling questions about how far people will go to gain acceptance. “ 2003

Bug chasers:

is the practice of pursuing the HIV positive individuals in order to contract HIV.

Gift givers:

are HIV-positive individuals who comply with the bug chaser's efforts to become infected with HIV.

- On July 16, 2012 the U.S. Food and Drug Administration approved Truvada, the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners. Truvada, taken daily, is 99% effective, when used for pre-exposure prophylaxis (PrEP) in combination with safer sex practices

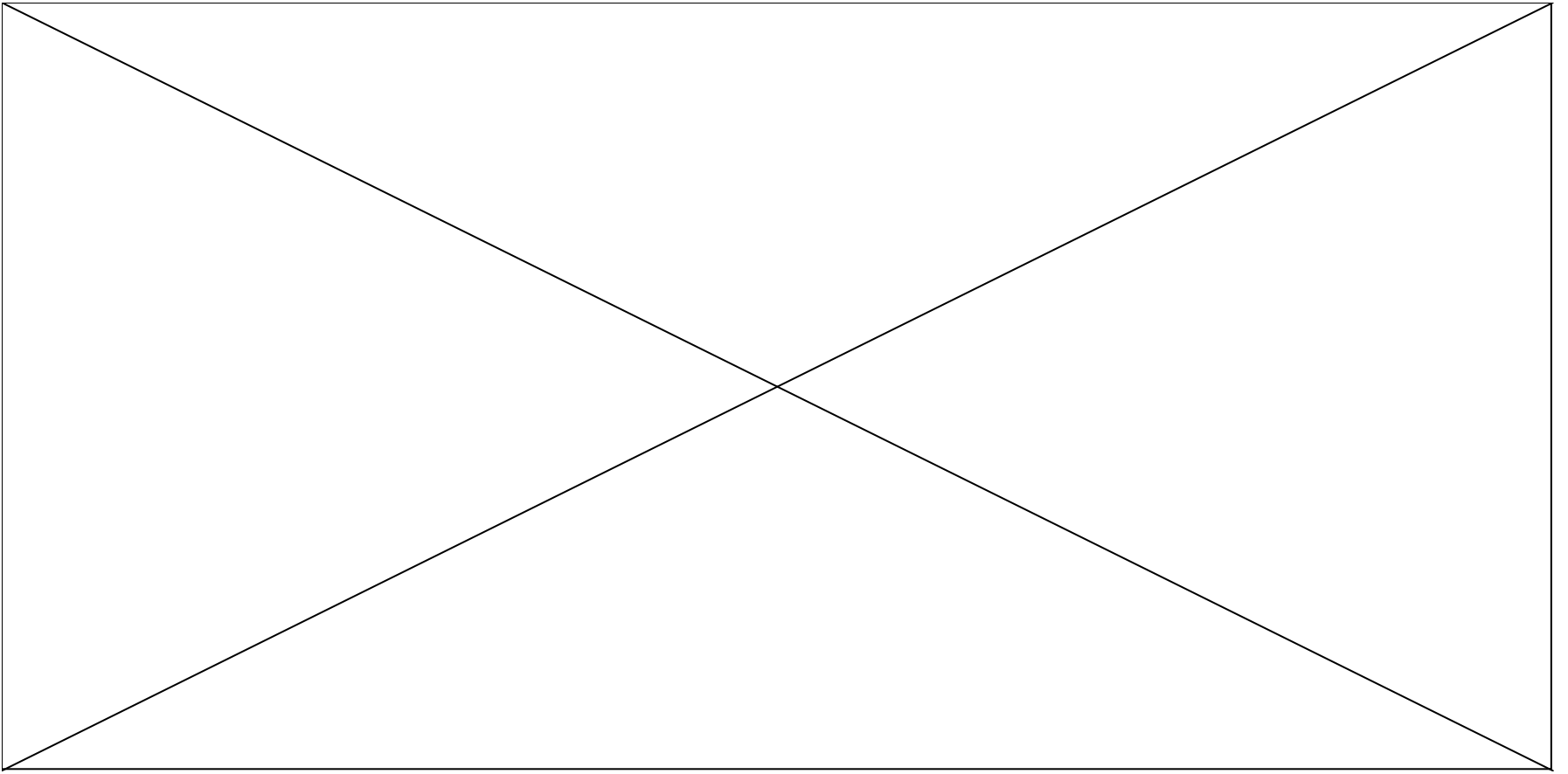
Cost –

HIV negative patient per year \$24,000

HIV positive patient per year \$480,000

PrEP





Illinois AIDS Confidentiality ACT-Amended Effective 1/1/2016

A new provision of the law provides two clear and separate paths for routine screening.

Opt-in: which states an individual or their representative are “offered” an HIV test and either accepts or declines- the facility provides pre-test information, and obtains consent verbally or in writing and documents the same for every individual

Opt-out: which states patients are notified that a test will be done unless they decline, requires a policy outlining the process, provide pre-test information either in a pamphlet, poster, or video and only document the declinations. No additional consent for testing is required-HIV testing maybe incorporated into the general consent

“ Step on the scale”



BEFORE



AFTER

HCV Infection

- There are many parallels between HIV infection and HCV infection
- Most patients are asymptomatic until very late in the course of disease
- Mortality due to chronic HCV now exceeds that for HIV infection in the USA
- Many more patients have HCV versus HIV
- HCV may be cured in the vast majority of patients with newer direct-acting HIV drugs



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**I AM WHERE I AM BECAUSE I BELIEVE IN ALL POSSIBILITIES." -
WHOOPI GOLDBERG**



