HOW PHARMACISTS CAN IMPACT HIV CARE:
A GENERAL OVERVIEW

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OBJECTIVES

• Discuss epidemiology of HIV in the United States
• Review HIV transmission
• Review DHHS’s HIV treatment guidelines
• Discuss HIV prevention methods and upcoming treatments/prevention
• Explore the role of pharmacists in treatment and prevention
CONFLICTS OF INTEREST

• None to disclose
HOW DOES TRANSMISSION OCCUR?

YOU CAN GET HIV VIA...
- Sex without a condom
- Passed from mother to baby
- Sharing injecting equipment
- Contaminated blood, transfusions, and organ transplants

YOU CAN'T GET HIV FROM...
- Kissing
- Hugging
- Sharing food
- Insect bites
- Toilet seats
- Bathing
- Sneezes and couchs
- Sweat
• As of the end of 2016, just over 1 million people over the age of 13 in the United States were living with HIV
  • ~15% are undiagnosed
• In 2017, the last year to have reported data, there were roughly 39,000 new HIV diagnoses.
  • The largest portion of these were among people age 20-39.
  • Black and Latinx people are the most disproportionately impacted.
  • The vast majority of transmissions are attributed to male to male sexual contact or sexual contact with transwomen.
  • Florida, California, Texas, New York and Georgia have the most cases numerically of all 50 states, the District of Columbia and 5 territories.

https://www.cdc.gov/hiv/statistics/overview/index.html
NEW DIAGNOSES IN 2017

https://www.cdc.gov/hiv/statistics/overview/ataglance.html
EPIDEMIOLOGY

- MSM – men who have sex with men
  - A group that includes all males who have sexual encounters with males regardless of how they self-identify
  - Also includes transwomen as gender identity is not a demographic category currently included. Instead, biological, birth assigned sex is included.
- Of note, women have higher lifetime risk among heterosexual persons and IV drug users compared to men.

https://www.cdc.gov/hiv/statistics/overview/index.html
EPIDEMIOLOGY

- When lifetime risk is broken down into race, men have far higher risk than women with white women having the lowest risk.
- The CDC did not include Asian, Indigenous American or other racial groups in their race demographic breakdown.
- Southern states largely make up the areas with highest lifetime risk.
- Health disparities and poverty are a large reason why this is the case.

https://www.cdc.gov/hiv/statistics/overview/index.html
WHAT DOES THIS MEAN?

• Black and Latinx transwomen and queer men (MSM) between the ages of 20 and 39, especially those that live in southern states, are disproportionately impacted by the HIV epidemic.
  • Black MSM have a lifetime risk of 50% of contracting HIV.
  • Latinx MSM have a lifetime risk of 25% of contracting HIV.
  • White MSM have a lifetime risk of 9% of contracting HIV.
  • Data does not currently delineate transgender persons from queer men.
• This does not mean they are the only ones impacted as HIV does not discriminate.
• This is largely due to a lack of healthcare access in both preventive and treatment services in these communities.

https://www.cdc.gov/hiv/statistics/overview/index.html
WHO SHOULD GET TESTED?

CDC recommends that everyone between the ages of 13 and 64 get tested at least once and that people with certain risk factors get tested more often.

Many people have HIV for years before they know it.

In 2015, nearly 40,000 people in the US received an HIV diagnosis:

- 1 in 2 had been living with HIV 3 years or more
- 1 in 4 had been living with HIV 7 years or more
- 1 in 5 already had the most advanced stage of HIV (AIDS)

Many people at high risk* for HIV aren’t getting tested every year:

- 59% heterosexuals at increased risk
- 42% people who inject drugs
- 29% gay and bisexual men

*People at high risk for HIV include: Transually active gay and bisexual men, ID people who inject drugs, and 27, heterosexuals who have sex with someone who is at risk for or has HIV.
WHO SHOULD GET TESTED? (CONT’D)

• If your last HIV test was negative you should get an HIV test if you answer “yes” to the following:
  • Are you a man or transwoman who has had sex with a man or transwoman?
  • Have you had vaginal or anal sex with someone who you either know or are uncertain is HIV positive?
  • Have you had more than one sexual partner?
  • Have you injected drugs and shared equipment (needles, syringes, etc.)?
  • Have you exchanged sex for drugs or money?
  • Have you been diagnosed with or treated for another STI, TB or hepatitis?
  • Have you had sex with someone who could answer “yes” to any of the above questions?

• Sexually active queer men and transwomen may benefit from more frequent testing every 3 to 6 months.

https://www.hiv.gov/hiv-basics/hiv-testing/learn-about-hiv-testing/who-should-get-tested
WHAT IS HIV? WHAT IS AIDS?

• HIV – human immunodeficiency virus
  • A retrovirus that infects CD4+ lymphocytes
  • If untreated, can lead to the development of AIDS
  • If treated and controlled, becomes a chronic inflammatory disease

• AIDS – acquired immunodeficiency syndrome
  • An HIV infection that has advanced in the destruction of the immune system, specifically CD4+ lymphocytes
  • Is defined by either the development of an “AIDS-defining illness” and/or a CD4 count less than 200 cells/mm³

• They are not interchangeable abbreviations
WHAT IS DRUG RESISTANCE?

- HIV develops genetic resistance to antiretrovirals vary rapidly in the face of suboptimal dosing, adherence or incomplete regimens
  - Resistance to multiple drugs within a given class is often common when viral resistance mutations develop
- Adherence of 90% or higher typically prevents the virus from creating resistance and maintains viral suppression
  - Regimens containing Dolutegavir, Bictegravir, Doravirine, Etravirine, Darunavir and/or Atazanavir are more forgiving on adherence to maintain this
  - Regimens without these drugs require greater adherence to prevent the creation of resistance and maintain viral suppression
WHAT DRUGS DO WE USE?

• NRTIs – nucleoside reverse transcriptase inhibitors
  • Emtriva (Emtricitabine)
  • Epivir (Lamivudine)
  • Retrovir* (Zidovudine)
  • Vemlidy (Tenfovir AF)
  • Videx* (Didanosine)
  • Viread (Tenfovir DF)
  • Zerit* (Stavudine)
  • Ziagen (Abacavir)

• NNRTIs – non-nucleoside reverse transcriptase inhibitors
  • Edurant (Rilpivirine)
  • Intelence (Etravirine)
  • Pifeltro (Doravirine)
  • Rescriptor* (Delavirdine)
  • Sustiva* (Efavirenz)
  • Viramune* (Nevirapine)

• INSTIs – integrase strand transfer inhibitors
  • Bictegravir (not available by itself)
  • Elvitegravir (not available by itself)
  • Isentress (Raltegravir)
  • Tivicay (Dolutegravir)

• PIs – protease inhibitors
  • Aptivus* (Tipranavir)
  • Crixivan* (Indinavir)
  • Invirase* (Saquinarvia)
  • Lexiva* (Fosamprenavir)
  • Lopinavir (not available by itself)
  • Prezista (Darunavir)
  • Reyataz (Atazanavir)
  • Viracept* (Nelfinavir)

• Els – entry inhibitors
  • Selzentry (Maraviroc)
  • Fuzeon* (Enfuvirtide)
  • Trogarzo* (Ibalizumab)

• PK Boosters
  • Tybost (Cobicistat)
  • Norvir (Ritonavir)

• * - no longer commonly used
COMBINATION PRODUCTS

- Single Tablet Regimens
  - **Atripla** (efavirenz/tenofovir DF/emtricitabine)
  - **Biktarvy** (bictegravir/tenofovir AF/emtricitabine)
  - **Complera** (rilpivirine/tenofovir DF/emtricitabine)
  - **Delstrigo** (doravirine/tenofovir DF/lamivudine)
  - **Genvoya** (elvitegravir/cobicistat/tenofovir AF/emtricitabine)
  - **Juluca** (dolutegravir/rilpivirine)
  - **Odefsey** (rilpivirine/tenofovir AF/emtricitabine)
  - **Stribild** (elvitegravir/cobicistat/tenofovir DF/emtricitabine)
  - **Symfi** (efavirenz/tenofovir DF/lamivudine)
  - **Symtuza** (darunavir/cobicistat/tenofovir AF/emtricitabine)
  - **Triumeq** (dolutegravir/abacavir/lamivudine)

- Protease Inhibitors w/ Booster
  - **Evotaz** (atazanavir/cobicistat)
  - **Kaletra** (lopinavir/ritonavir)
  - **Prezcobix** (darunavir/cobicistat)

- Combination NRTIs
  - **Cimduo** (tenofovir DF/lamivudine)
  - **Combivir** (zidovudine/lamivudine)
  - **Descovy** (tenofovir AF/emtricitabine)
  - **Epzicom** (abacavir/lamivudine)
  - **Trizivir** (abacavir/lamivudine/zidovudine)
  - **Truvada** (tenofovir DF/emtricitabine)

- * - no longer commonly used
DHHS HIV TREATMENT GUIDELINES

• Someone just tested positive and has never been on treatment what do I do?
  • Linkage to HIV care provider
  • Labs to order:
    • Viral load
    • CD4 count
    • Resistance panel
    • Chemistry panel
    • Hepatitis panel
    • HLA*B5701 (if considering using abacavir)
    • Lipids
  • Consider rapid start or rapid entry onto therapy
• What if I want to start treatment before labs return?
  • Dolutegravir or boosted darunavir with tenofovir (DF or AF) and either emtricitabine or lamivudine can be used until resistance results return and then kept or changed based on results
  • Biktarvy is being thought of as having a possible use for “rapid start” with many providers using it as such but has not yet been recommended by the DHHS for use in this way

I have lab results back, what do I start for HIV treatment?

DHHS Recommended:
- INSTI-based
  - Bictegravir/Tenofovir AF/Emtricitabine
  - Dolutegravir/Abacavir/Lamivudine or Dolutegravir + Tenofovir (DF or AF)/Emtricitabine
  - Raltegravir + Tenofovir (DF or AF)/Emtricitabine
- DHHS Recommended Under Certain Circumstances:
  - INSTI-based
    - Elvitegravir/Cobicistat/Tenofovir (DF or AF)/Emtricitabine
    - Raltegravir + Abacavir/Lamivudine
  - PI-based
    - Darunavir/Cobicistat/Tenofovir AF/Emtricitabine or Darunavir/Cobicistat + (Tenofovir DF/Emtricitabine or Abacavir/Lamivudine)
    - Darunavir + Ritonavir + (Tenofovir DF or AF)/Emtricitabine or Abacavir/Lamivudine
    - Atazanavir/Cobicistat + Tenofovir (DF or AF)/Emtricitabine
    - Atazanavir + Ritonavir + Tenofovir (DF or AF)/Emtricitabine
  - NNRTI-based
    - Darunavir/Cobicistat + (Lamivudine or Emtricitabine)
    - Darunavir/Cobicistat + (Abacavir or Lamivudine)
    - Darunavir + Ritonavir + (Lamivudine or Emtricitabine)
    - Darunavir + Ritonavir + Raltegravir (BID dosing for all)
    - Dolutegravir + (Lamivudine or Emtricitabine)

DHHS Recommended if Tenofovir and Abacavir cannot be used:
- Darunavir/Cobicistat + (Lamivudine or Emtricitabine)
- Darunavir + Ritonavir + (Lamivudine or Emtricitabine)
- Darunavir + Ritonavir + Raltegravir (BID dosing for all)
- Dolutegravir + (Lamivudine or Emtricitabine)

- * - only use if HLA*B5701 negative
- ^ - only use if VL < 100,000 copies/mL
- ~ - only use if CD4 > 200 cells/mm³

Consider drug interactions and comorbid conditions when selecting regimen and if fixed dosed combination tablets may need to have their components given separately
- Renal or hepatic dosing
- Insurance coverage
- Emtricitabine and Lamivudine are interchangeable and may be substituted for each other as listed above to include substituting the combination product Tenofovir DF/Lamivudine for Tenofovir DF/Emtricitabine

• CD4 < 200
  • PCP Prophylaxis
    • SMX/TMP (DS or SS) QD or DS TIW
    • Dapsone 100mg QD
    • Atovaquone 1500mg QD
  • May be stopped once CD4 > 200 x 3 months or VL undetectable + CD4 > 100 x 3 months on ARVs
• CD4 < 150
  • Histoplasmosis Prophylaxis (regional only)
    • Itraconazole 200mg QD
  • May be stopped once CD4 > 200 x 3 months on ARVs
• CD4 < 100
  • Toxo Prophylaxis (antigen positive only)
    • SMX/TMP (DS or SS) QD or DS TIW
    • Dapsone 50mg QD or 200mg QW + Pyrimethamine 75mg QW + Leucovorin 25mg QW
    • Atovaquone 1500mg QD
    • Atovaquone 1500mg QD + Pyrimethamine 75mg QD + Leucovorin 25mg QD
  • May be stopped once CD4 > 200 x 3 months on ARVs
• CD4 < 50 and not on ARVs
  • MAC Prophylaxis
    • Azithromycin 600mg BIW or 1200mg QW
    • Clarithromycin 500mg BID
    • Rifabutin 300mg QD
  • May be stopped once on ARVs

• What if my patient has been on treatment for a while and is not taking a “traditional” regimen?
  • A recommended regimen includes at least two fully active drugs from different drug classes
    • May be split up versions of single tablet regimens due to reduced renal or hepatic function
    • May be a modification of “traditional” 2NRTI + 1 (PI, INSTI, NNRTI or EI)
    • “Traditional” regimens are three drugs from 2 different drug classes as described above and may occasionally contain more drugs if necessary for dosing simplification or synergy
  • Insure all PIs (excluding Nelfinavir and unboosted dosing of Atazanavir, Indinavir or Fosamprenavir) are given with a booster.
    • Boosters can either be stand alone as Tybost or Norvir or may be co-formulated in Genvoya, Stritsild, Prezcobix, Evotaz or Kaletra
    • Cobicistat and Ritonavir should not be used together
    • Once daily regimens with multiple drugs needing PK boosting do not need to double up the dosing of the boosting agent

THINGS TO LOOK OUT FOR

• Drug interactions*:
  • PIs and PK boosting agents
    • Statins
    • Anticoagulants
    • Psychiatric agents
    • Corticosteroids
    • HCV DAAs
    • CYP inducers and substrates
  • INSTIs
    • Metformin
    • Polyvalent Cations (Ca, Fe, Mg, Al, etc)
  • NNRTIs
    • Psychiatric agents
    • HCV DAAs
  • Tenofovir DF
    • HCV DAAs
  • Etravirine
    • Dolutegravir (ok if given with ritonavir boosted PI)
    • Maraviroc
    • Cobicistat
    • CYP substrates
  • Rilpivirine and Atazanavir
    • Acid suppressing agents (PPIs, H2RAs, Antacids, etc)
  • Maraviroc
    • Etravirine
    • PIs and boosting agents
    • CYP inhibitors and inducers

* - This list only includes commonly seen drug interactions and should not be considered totally inclusive
THINGS TO LOOK OUT FOR (CONT’D)

- **Viral Suppression**
  - Goal is undetectable
  - Patient is not at risk of developing AIDS
  - Patient is not at risk AIDS related diseases or opportunistic infections
  - Patient is not at risk of transmitting HIV sexually
  - Blips may occur from time to time as latent CD4 cells may periodically reactivate

- **Renal Function**
  - NRTIs excluding abacavir
  - Cobicistat
  - Maraviroc
  - Nevirapine, Delavirdine

- **Hepatic Function**
  - PIs and boosting agents
  - Abacavir
  - Maraviroc
  - Efavirenz, Nevirapine, Delavirdine

- **CD4 count / Immunosuppression**
  - Goal is above 200 but ideally above 500
  - Opportunistic infections are at much higher risk below 200 especially if VL is elevated
    - Avoidance of risk factors
    - Vaccinations
    - Prophylaxis and treatment meds
THINGS TO LOOK OUT FOR (CONT’D)

• Complete regimen
  • Make sure the entirety of a patient’s regimen is picked up together so that a patient always has their complete ARV regimen
    • If unsure about what complete regimen is supposed to be then confirm with patient’s medical provider prior to dispensing
    • Consider providing partial fills of components of regimen if patient’s refills are not synced together on same day

• Adherence
  • Adherence of 90% or more to antiretrovirals is paramount to prevention of the virus developing resistance, maintenance of viral suppression and prevention of transmission
    • If possible, place all HIV patients on automatic refill program
    • Keep antiretrovirals in stock and for patients who routinely get them
    • If possible, provide patients with adherence packaging, pill dividers or other adherence tools
    • Stay on top of making sure refill requests are sent and responded to in a timely manner
THINGS TO LOOK OUT FOR (CONT’D)

• HBV Co-infection
  • Utilize fully suppressive ARV regimen that includes tenofovir (DF or AF) and either emtricitabine or lamivudine
  • If not feasible, the addition of entecavir is recommended
  • Discontinuation of any of these agents may cause an exacerbation of HBV

• Pregnancy
  • Tenofovir DF, Emtricitabine, Lamivudine, Abacavir, Zidovudine, Ritonavir and Rilpivirine (excluding Trizivir) are recommended for use during pregnancy without dose adjustment
  • Atazanavir, Darunavir, Lopinavir, Efavirenz and Raltegravir have alternative dosing schedules or amounts for pregnant persons
  • Efavirenz and Dolutegravir are not recommend for use currently in first trimester
  • Bictegravir, Tenofovir AF, Ibalizumab, Fosamprenavir and Doravirine don’t have sufficient data to currently recommend use during pregnancy
  • All other ARVs are to be avoided for use during pregnancy
THINGS TO LOOK OUT FOR (CONT’D)

- Metabolic Disorders
  - ARV induced
    - Hyperlipidemia
    - Hypertension
    - Diabetes
    - Renal disease
    - GI conditions
    - Osteoporosis
    - Fat redistribution/Obesity
  - PIs, Efavirenz, Tenofovir DF, Abacavir and INSTIs are common causes
  - HIV induced
    - Renal disease
    - Cardiovascular disease
    - GI conditions
    - Earlier onset than in HIV negative population

- Psychiatric Disorders
  - ARV induced
    - NNRTIs
  - HIV induced
    - Dementia
PREVENTION METHODS

• PrEP – pre-exposure prophylaxis
  • HIV negative person taking ARVs before HIV exposure
  • Every 3 month screening for HIV and other STIs
  • Truvada
    • Daily vs. event driven

• PEP – post exposure prophylaxis
  • HIV negative person taking ARVs after HIV exposure
  • Needle stick or other occupational
  • Sexual assault
  • Potential sexual or blood exposure from person of unknown or positive HIV status
  • Must start within 72 hours of exposure
  • Regimen
    • Stribild, Complera, Atripla, Symfi, Delstrigo or (Prezcobix, Evotaz, Isentress or Tivicay) + Truvada for 4 weeks
    • Patients who may receive multiple courses of PEP during a given 12 month period or whom are otherwise candidates for PrEP can and should immediately transition to PrEP after completion of 4 week PEP regimen

• TasP – treatment as prevention
  • HIV positive person taking ARVs and maintaining viral suppression
  • U=U (undetectable = untransmittable)
WHAT COULD BE COMING UP?

- Injectable therapies for both PrEP and TasP
- Dual therapy
- Long acting therapies
- Various dosing formations
WHAT ROLE DO PHARMACISTS HAVE?

- Adherence, adherence, adherence
  - Pharmacists have the greatest impact on patient adherence
    - Adherence packaging
    - Adherence counseling
    - Adherence reminders
    - Copay or cost assistance
    - Refill requests
    - Retention in care

- Counseling on how to take meds
  - Rilpivirine with chewed meal
  - Efavirenz on empty stomach
  - PIs and boosting agents with food
  - Addressing side effects
Regimen simplification recommendations
- Simple regimens with low side effect profiles
- NRTIs, Rilpivirine, Doravirine, Etravirine, INSTIs, Darunavir and Maravirocin generally considered to have low side effect profiles
- Keeping in mind resistance profiles and drug interactions, switching between drugs in same drug class in an effort to simplify regimen generally maintains viral suppression
- Dual therapy recommendations where feasible

Prevention
- Adherence to TasP
- Adherence to PEP
- Adherence to PrEP
- Recommending patient for PrEP or PEP services if needed

Treatment
- Pharmacist administered POCT for HIV
- Referrals to HIV care providers
HIV CARE CONTINUUM:

The series of steps a person with HIV takes from initial diagnosis through their successful treatment with HIV medication.

1. Diagnosed with HIV
2. Linked to care
3. Engaged or retained in care
4. Prescribed antiretroviral therapy
5. Achieved viral suppression
CARE CONTINUUM ENGAGEMENT RATES

HIV Care Continuum, United States, 2014
An estimated 1.1 million people are living with HIV in the United States.

HIV Care Continuum, by Age, U.S., 2014

HIV Care Continuum, by Race/Ethnicity, U.S., 2014

HIV Care Continuum, by Sex, U.S., 2014

HIV Care Continuum, by Transmission Route, U.S., 2014

Source Centers for Disease Control and Prevention

THANKS!!!

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