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HIV CARE & TREATMENT

# Putting the PharmD in Adherence: An Evaluation of the Impact of a Clinical Pharmacist on Viral Suppression Rates

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# Disclaimer



The presenter does not have any conflicts of interest related to this research.

# Learning Objectives:



- ❖ Understand the relationship between medication adherence and viral suppression
- ❖ Describe the barriers that prevent medication adherence in the HIV patient population
- ❖ Explain the contribution of a clinical pharmacist on viral suppression rates over time

# Medication Adherence

Why does it matter?

# Medication Adherence vs Medication Compliance



## ADHERENCE

When a patient takes at least 90% of prescribed doses of a medication as recommended by the prescriber

- Patient centered
- Clinician-patient collaboration
- Information is exchanged
- Activities are negotiated
- Rules fit patient lifestyle
- Discuss, negotiate, MOTIVATE

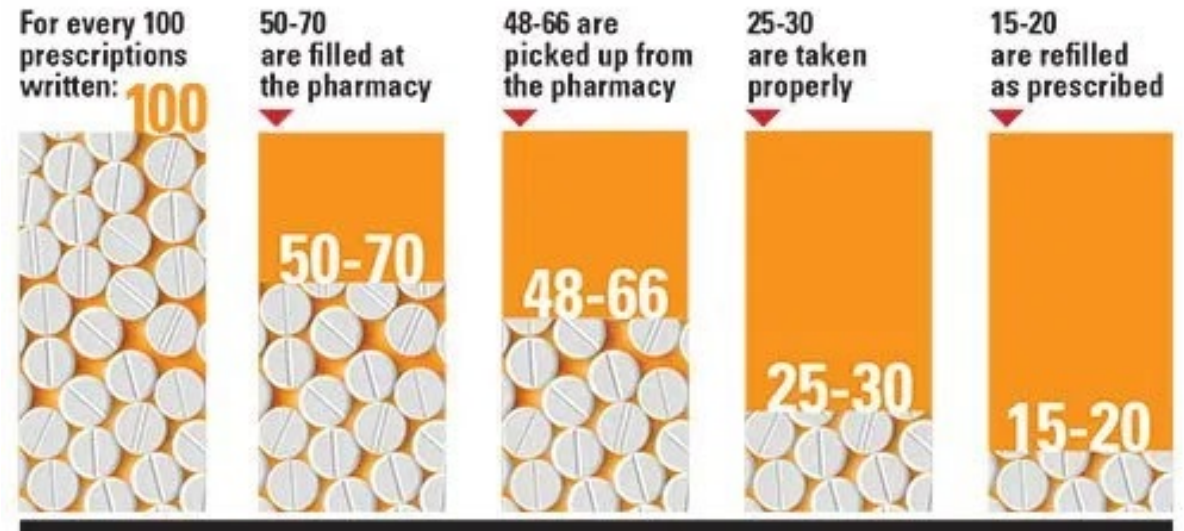
## COMPLIANCE

When a patient passively follows the prescriber's orders

- Clinician centered
- Clinician dominance
- Information is dictated
- Goal is patient obedience
- Rules are dictated
- Persuade, coerce
- Patient does not necessarily agree with plan

# Medication Adherence

- Most adults in the United States **do not** adhere to their medication regimen as prescribed.
- Research has suggested that:
  - 50% of people with chronic diseases do not take medications as prescribed
  - 16% of patients fail to fill a new prescription
  - 50% of patients stop taking a new medication after only 6 months
  - 33%-69% of hospital re-admissions are due to non-adherence



Source: National Association of Chain Drug Stores, Pharmacies: Improving Health, Reducing Costs, July 2010. Based on IMS health data.

# Types of Medication Adherence



## TYPES OF NON-ADHERENCE

Fulfillment	Non-Persistence	Non-Conforming
<ul style="list-style-type: none"><li>• RX is never filled</li></ul>	<ul style="list-style-type: none"><li>• Stops medication on their own because they do not understand</li></ul>	<ul style="list-style-type: none"><li>• Medication is not taken as prescribed</li><li>• Skipping doses</li><li>• Incorrect dosing</li><li>• Incorrect timing of doses</li></ul>

- **Unintentional Non-Adherence (30% of all cases)**
  - Resource Limitations
  - Forgetfulness
  - Complicated Dosing
  - Change in Personal Schedule
- **Intentional Non-Adherence (70% of all cases)**
  - Beliefs
  - Expectations
  - Attitudes
  - Side Effects
  - Feeling as if medications are ineffective
  - Feeling as if medications are not needed

## Five Dimensions of Adherence

### Social and Economic

- Limited language proficiency
- Low health literacy
- Unstable living conditions or homelessness
- Lack of health insurance
- Medication costs

### Health Care System

- Patient-Provider relationship
- Long wait times
- Lack of care continuity
- Restricted formularies

### Condition-Related

- Lack of symptoms
- Severity of symptoms
- Depression
- Psychotic disorders

### Therapy-Related

- Complexity of the medication regimen
- Duration of therapy
- Frequent changes
- Actual or perceived side effects

### Patient-Related

- Visual, hearing, cognitive impairment
- Knowledge about disease
- Perceived risk/susceptibility to disease
- Perceived benefit of treatment
- Motivation and confidence



# Medication Adherence: Antiretrovirals

## Our patient goal is >95% adherence

- 1 missed dose or less of a single tablet regimen in a 30 day period
- Required to achieve full and durable viral suppression
- Overall adherence rates are variable

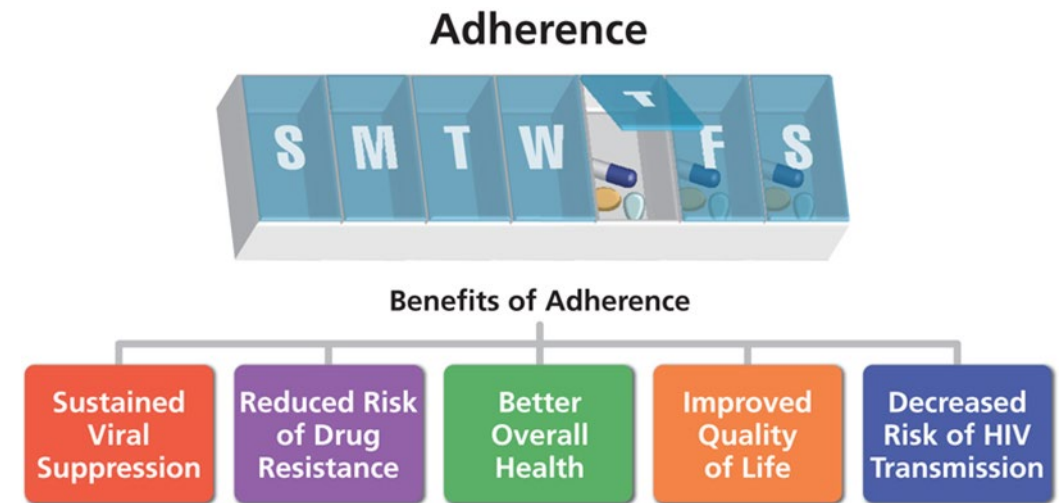


Image source: <https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/777/adherence>

# ARV Adherence: A Public Health Perspective

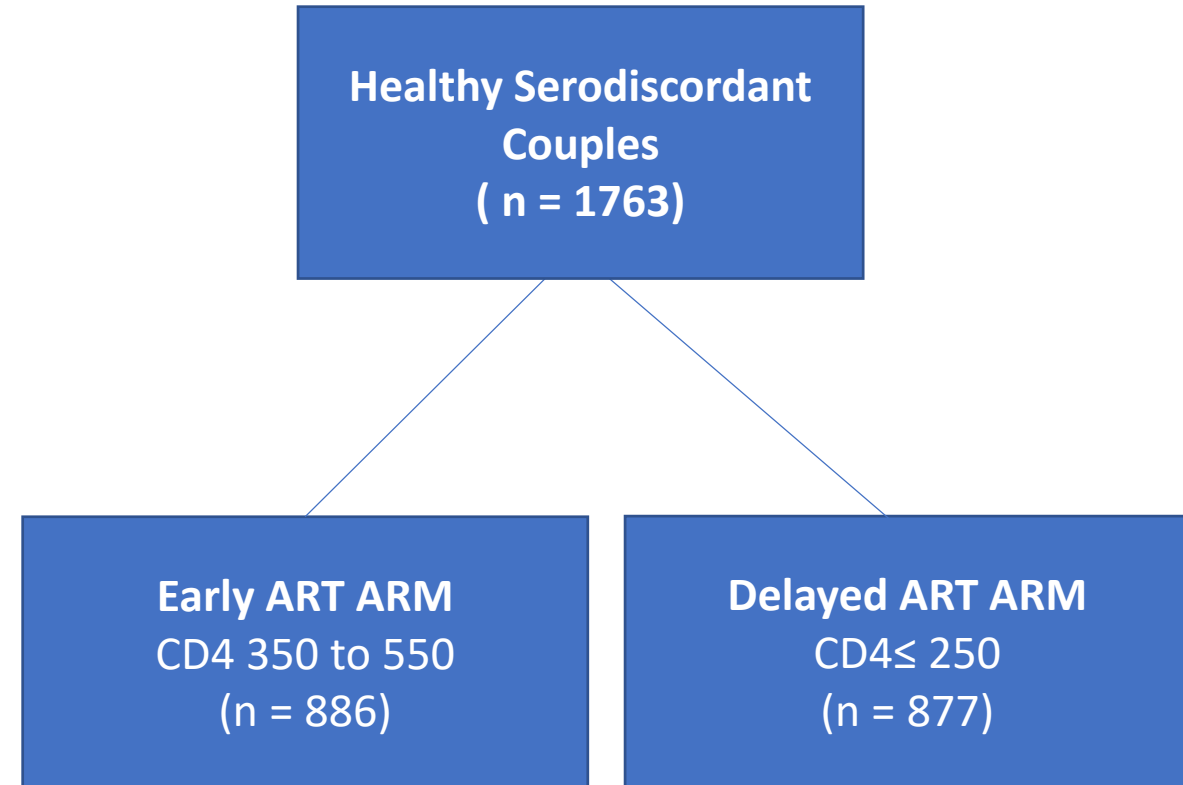


## Undetectable = Untransmittable & Treatment as Prevention

- Data started being published around 2000 to suggest a possible correlation between transmission and VL
  - Quinn TC, Wawer MJ, Sewankambo N, et al.
    - 415 serodiscordant couples
    - 90 of the 415 negative partners seroconverted
    - Transmission risk was significantly higher among subjects whose partner's VL not suppressed
    - No instances of transmission with VL < 1500 copies/mL
- Concepts solidified by three studies published since 2011:
  - HPTN 052, PARTNER, Opposites Attract

# HPTN 052: Study Design

- Phase III, two-arm, randomized, controlled, multi-center trial
  - Determined if ART can prevent the sexual transmission of HIV-1 in serodiscordant couples
  - 1,763 HIV serodiscordant couples at 13 sites in 9 countries
  - Majority of the couples were heterosexual (97%)
- HIV+ partners were assigned to two arms:
  - “Early” - start ART when CD4 350-550
  - “Delayed” – start ART when CD4  $\leq 250$  cells/mm<sup>3</sup>



# HPTN 052: Results



- Genetic analysis was used to determine if any transmission was `linked` or `unlinked`
- 877 couples in the delayed ART group
  - 43 linked HIV transmissions
- 886 couples in the early ART group
  - 3 linked transmission
- 26 total unlinked transmission events also occurred
- Early ART was associated with a 93% lower risk of linked partner infection (HR, 0.07; 95% CI, 0.02 to 0.22)
- No linked infections were observed when VL was stably suppressed by ART

# HPTN 052: Adherence



- Adherence was assessed via:
  - Pill count
  - Self report
- All participants received adherence counseling
  - 82% of participants were adherent via pill count at 1 month
  - 83.3% of participants were adherent via pill count at 1 year
  - 88.8% reported less than perfect adherence at 1 month
  - 84.2% reported less than perfect adherence at 1 year

- At 1 month, the most frequent reasons for non-adherence were:
  - Forgot (40.4%)
  - Traveling away from home (19.3%)
  - Wanted to avoid side effects (17.0%)
  - Busy doing other things (9.4%)
  - Other illness or health problems got in the way (8.2%)
  - Ran out of pills (6.4%)
- At 1 year, the most frequent reasons given for non-adherence were:
  - Forgot (45.1%)
  - Busy doing other things (20.7%)
  - Traveling away from home (22.6%)
  - Ran out of pills (14%)

- Prospective observational study
  - Evaluated the rate of within-couple HIV transmission during periods of sex without condoms and when the HIV-positive partner had VL < 200 copies/mL
  - 2 phases of the study took place at 75 sites in 14 European countries
    - Phase 1 included MSM & Heterosexual couples
    - Phase 2 included MSM only
  - Phase 1: 1166 HIV serodiscordant couples, 1238 total couple years
  - Phase 2: 782 HIV serodiscordant couples, 1593 total couple years

- To be included in the analysis, partners had to report:
  - Condomless vaginal or anal sex in the months before enrollment
  - Continued condomless sex during the study period
  - No use of PrEP or PEP
  - Latest VL in initially positive partner below 200 copies/mL on ART
- Phase 1 Results:
  - 11 transmissions (10 MSM; 1 heterosexual)
  - 0 linked transmissions occurred
- Phase 2 Results:
  - 15 transmissions
  - 0 linked transmissions occurred



# PARTNER Studies: Adherence



- Phase 1 Adherence Data
  - Percent of subject groups self reporting >90% adherence to ART:
    - 93% of heterosexual men
    - 94% of heterosexual women
    - 97% of MSM
  - Very few reported missing ART for more than 4 consecutive days
- Phase 2 Adherence Data
  - 98% HIV-positive partners reported adherence of >90% at study entry
  - 92% of follow up years found adherence was >90%
  - 5% of follow up years was reported as missing ART for more than 4 consecutive days

# Opposites Attract

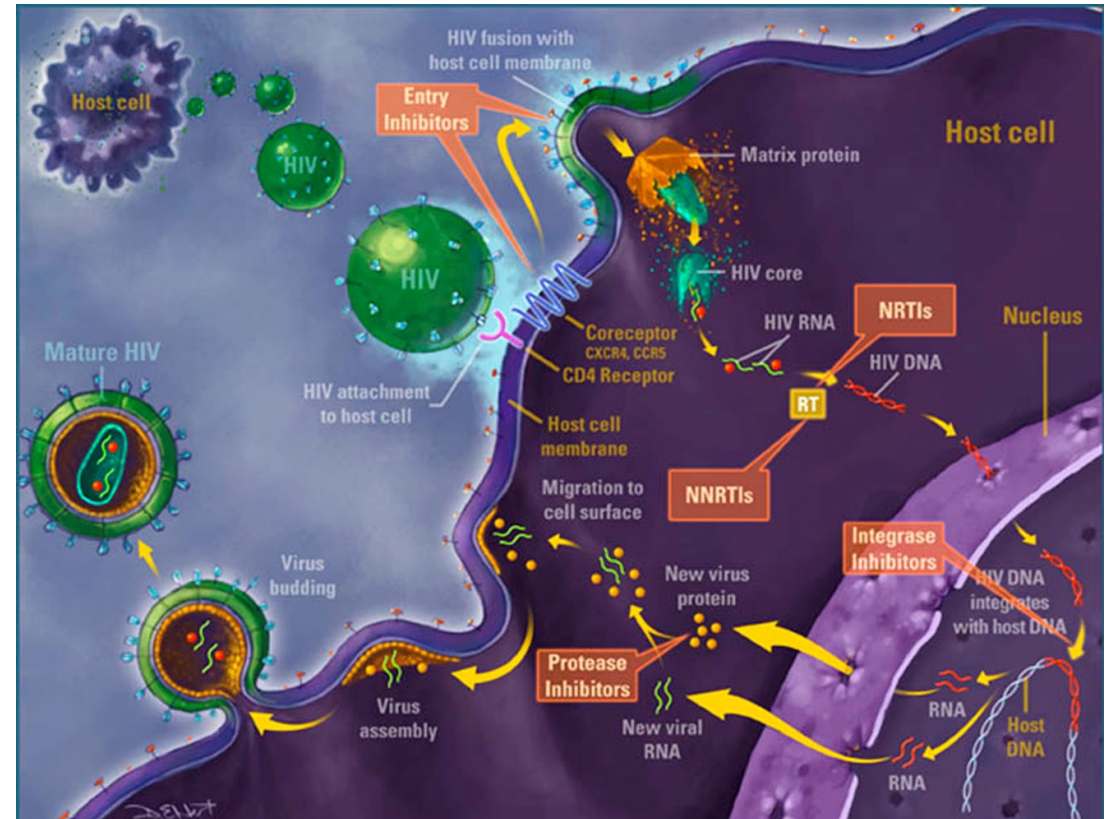


- Prospective observational cohort study
  - Determined whether HIV is transmitted between MSM serodiscordant couples when the HIV-positive partner is on ART
- 343 HIV serodiscordant MSM couples at 15 sites in 3 countries
  - Reported Condomless Anal Intercourse (CLAI) acts at each follow up visit
- 258 (75%) of 343 HIV-positive partners had VL < 200 copies/mL
- 115 (34%) of 343 HIV-negative partners used daily PrEP
- A total of 16 800 CLAI acts were reported
  - 3 transmissions
  - 0 linked transmissions

# ARV Adherence: A Public Health Perspective

## Goals of ARV therapy:

- Maximally & durably suppress viral load
- Reduce HIV-associated morbidity
- Prolong survival
- Improve Quality of Life
- Restore and preserve immune system function
- **Prevent HIV transmission**



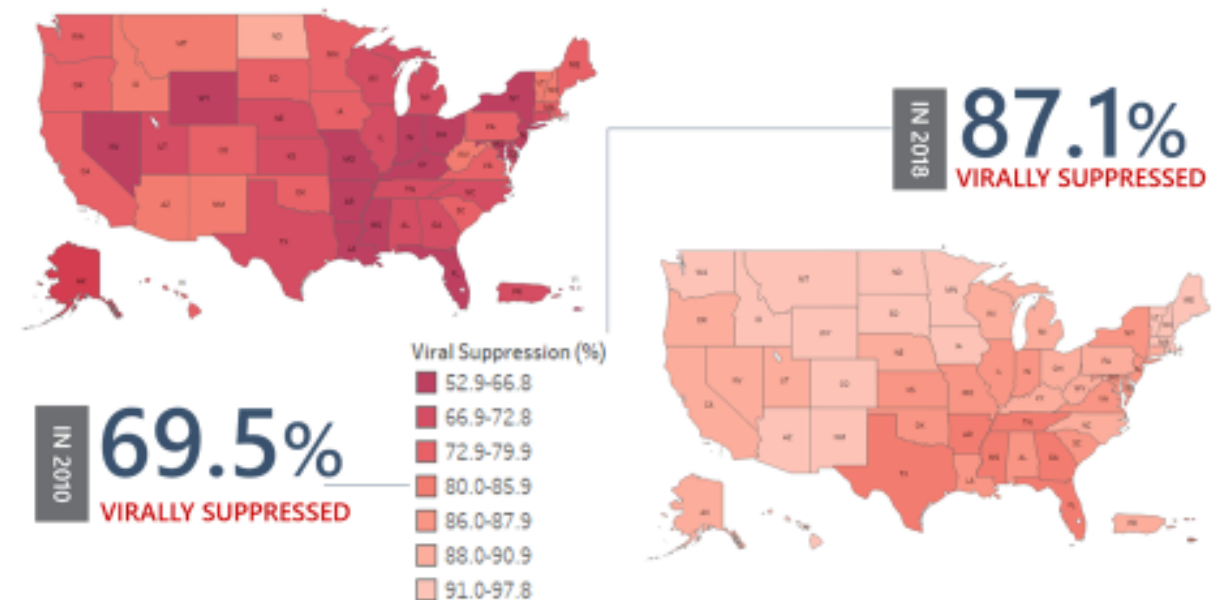
Source: Kalapila, Aley G. and Jeanne M Marrazzo. "Antiretroviral Therapy for Prevention of Human Immunodeficiency Virus Infection." *The Medical clinics of North America* 100 4 (2016): 927-50 . Courtesy of David H. Spach, MD, University of Washington, Harborview Medical Center, Seattle, WA.

# Viral Suppression Data: Who is at Risk of Non-Adherence?

## 2017 CDC Data Reports:

- 62.7% of persons diagnosed with HIV are virally suppressed
- Groups with lowest viral suppression rates:
  - 13–24 years (56.9%)
  - Blacks (57.4%)
  - Males who inject drugs (52.0%)

## Viral Suppression among RWHAP Clients, by State, 2010 and 2018—United States and 2 Territories<sup>a</sup>



Viral suppression: ≥1 OAHG visit during the calendar year and ≥1 viral load reported, with the last viral load result <200 copies/mL.  
<sup>a</sup> Puerto Rico and the U.S. Virgin Islands.

Source: HRSA, Ryan White HIV/AIDS Program Services Report (RSR) 2018. Does not include AIDS Drug Assistance Program data.

# Pharmacists are the Medication Experts



- **Many studies show pharmacist interventions improve outcomes**
  - Morgado MP, Morgado SR, Mendes LC, et al.
    - Systematic review of 15 studies in hypertension patients
    - 88% improvement in clinical outcomes
    - 44% increase in medication adherence after pharmacist interventions
  - Taitel M, Jiang J, Rudkin K, et al.
    - A retrospective cohort study
    - Pharmacists provided face-to-face counseling to address adherence barriers to statins
    - Patients who received counseling were significantly more adherent at 12 months, 120 days, and 365 days
  - Erku DA, Ayele AA, Mekuria AB, Belachew SA, Hailemeskel B, Tegegn HG
    - Prospective randomized controlled study in patients with type 2 diabetes mellitus
    - Pharmacists provided care plans and education.
    - Increase in medication adherence from baseline to 3 and 6 months in the intervention group
    - Intervention group had 52.1% fewer hospital admissions at 6 months

Morgado MP, Morgado SR, Mendes LC, et al. *Am J Health Syst Pharm.* 2011;68:241-253.

Taitel M, Jiang J, Rudkin K, et al. *Patient Prefer Adherence.* 2012;6:323-329.

Erku DA, Ayele AA, Mekuria AB, Belachew SA, Hailemeskel B, Tegegn HG. *Pharm Pract (Granada).* 2017;15(3):1026.

# Pharmacists Improving HIV Adherence Rates



Ma A, Chen DM, Chau FM, Saberi P

- Retrospective cohort study of 73 HIV-positive patients
- Assessed whether interventions by an HIV clinical pharmacy specialist had an effect on ARV adherence
- Interventions included:
  - Using combination medications
  - Reducing pill burden
  - Minimization of adverse effects
  - Education on adherence
- Interventions resulted in an improvement in adherence from 81% to 89%

# Pharmacists Improving Viral Suppression Rates



Dilworth TJ, Klein PW, Mercier RC, Borrego ME, Jakeman B, Pinkerton SD

- Pilot study with a pretest-posttest design
  - Examined the effect of a pharmacy adherence clinic on patient HIV viral load and CD4 count over 6 months
  - 28 patients with documented adherence problems were referred to the clinic; 16 patients completed the program
  - Adherence clinic was 2 half day sessions ONLY
- Interventions included:
  - Medication Reconciliation
  - Assessing patient adherence to ART
  - Managing ART side effects and drug interactions
  - Using motivational interviewing techniques to encourage ART adherence
  - Screening for opportunistic infection prophylaxis
  - Screening for ART adherence barriers
  - Providing education on medications and HIV
  - Developing patient ART regimens
- Median HIV viral load decreased from 48,000 copies/mL at baseline to all participants having an undetectable viral load at 6 months

# Pharmacists Improving HIV Care Outcomes



Saberi P, Dong BJ, Johnson MO, Greenblatt RM, Cocohoba JM

- Systematic review of 32 publications
- Assessed the impact of an HIV clinical pharmacist on treatment outcomes
  - Majority examined the impact of pharmacists in HIV ambulatory care clinic setting (63%) and outpatient community pharmacies (26%)
- Pharmacist roles included:
  - Medication adherence counseling
  - Patient education
  - ARV regimen selection
  - ARV initiation, discontinuation, and dose adjustment for renal/hepatic impairment
  - Monitoring for ARV adverse effects and drug interactions
- Involvement of an HIV clinical pharmacy specialist was associated with clinically and statistically significant improvements in ARV adherence
- Also indicated that **HIV clinical pharmacy specialist's care was associated with greater viral load suppression.**



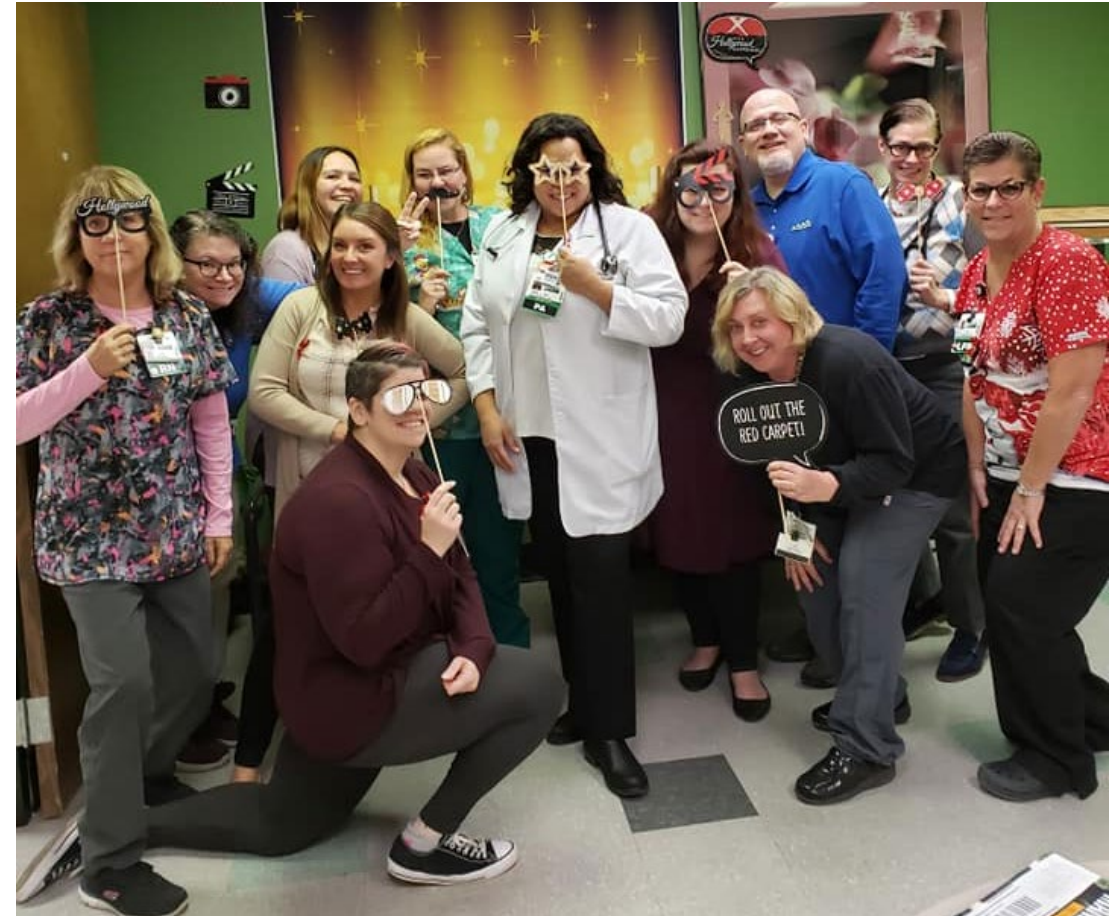
# Our Clinic Model

Erie County Medical Center, Buffalo, New York



# The 'YOU' Center for Wellness

- The “Designated AIDS Center” of Western New York
  - Service 8 counties of Western New York
- Multidisciplinary Approach
  - Social work
  - Dietary
  - Mental Health
  - Substance Abuse
  - Pharmacy
  - Nursing
  - Prescribers

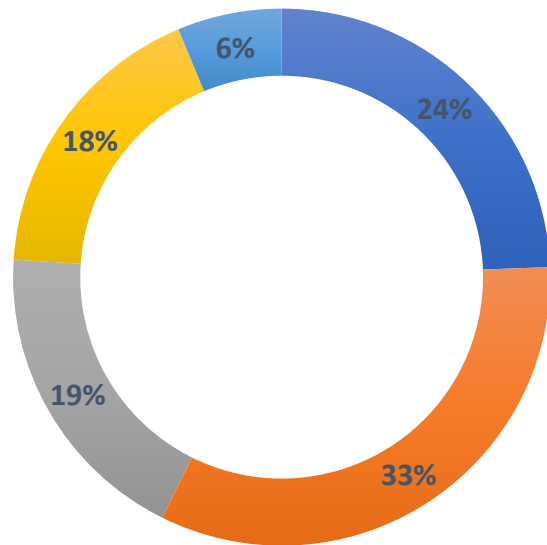


# Clinic Demographics (2019 RSR Report)



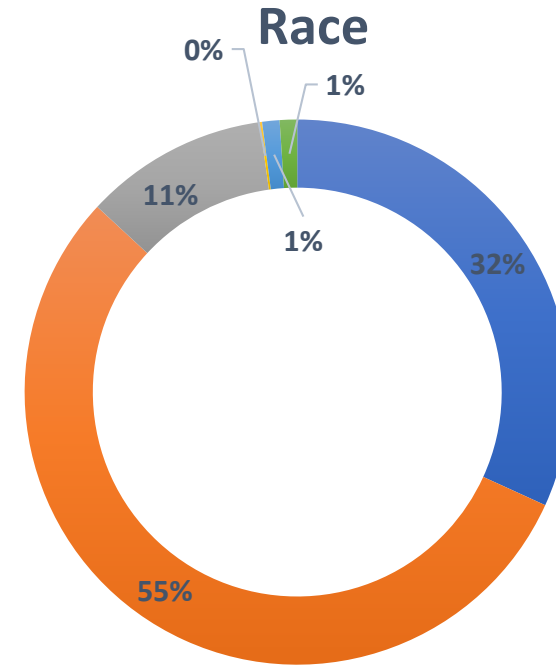
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## Age



■ 60's+ ■ 50's ■ 40's ■ 30's ■ 20's

## Race



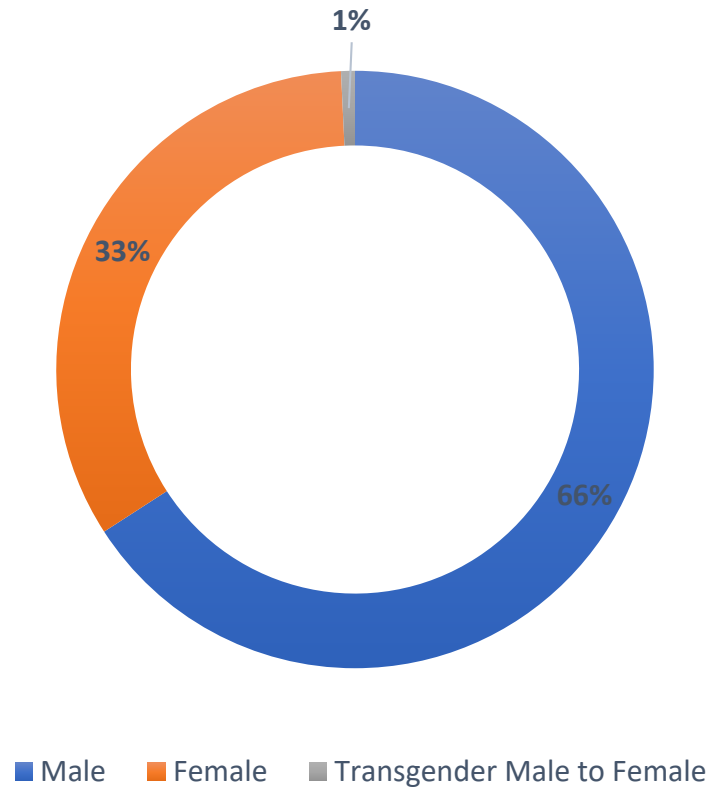
■ White  
■ Black  
■ Hispanic or Latino  
■ Native Hawaiian/Pacific Islander

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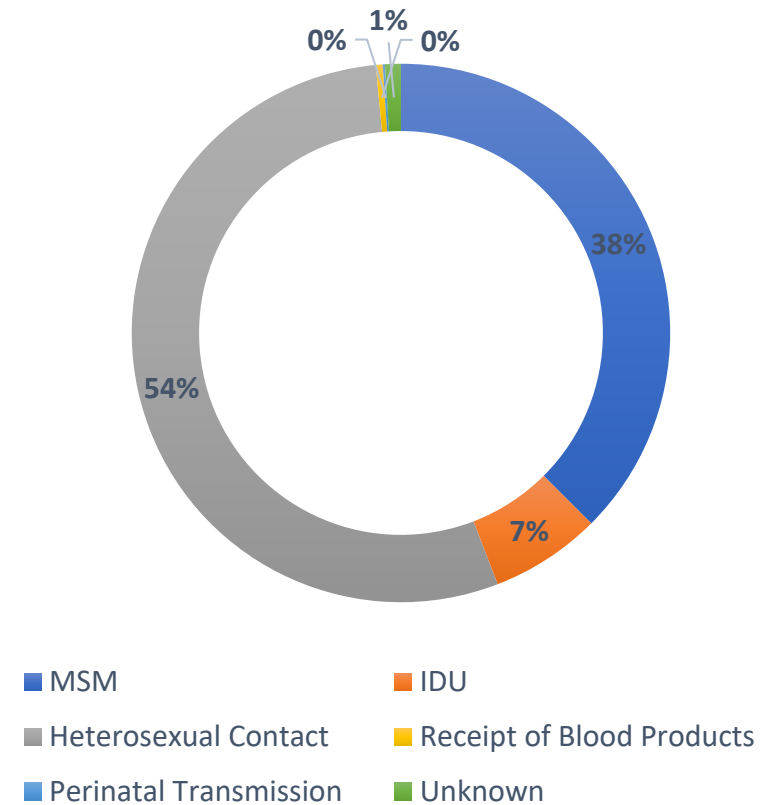


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### Gender



### HIV Risk Factor



# Role of the Clinical Pharmacist



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- Medication Reconciliation
- Transitions of Care
- Drug Regimen Design
- Adherence Counseling
- Side Effect Management
- Chart Reviews
- Primary Care Disease State Management
- Monitoring and Follow-Up
- Liaison between patient, pharmacy, and prescriber



# Adherence Improvement Strategies

# Identifying Non-Adherence and Barriers to Adherence



- Ask every patient about barriers at every visit
  - Copay, pharmacy, mental health, side effect, etc. concerns
  - Provide continued patient education on disease state and medication adherence
- Use a team approach
  - Every team member assesses adherence at every visit
  - Patients may tell different members of the team different information
  - Team communication is an important factor
- Utilize community pharmacies
  - RX fill histories are a good predictor of non-adherence
- Monitor viral loads in those who are not virally suppressed



## Five Dimensions of Adherence

### Social and Economic

- Limited language proficiency
- Low health literacy
- Unstable living conditions or homelessness
- Lack of health insurance
- Medication costs

### Health Care System

- Patient-Provider relationship
- Long wait times
- Lack of care continuity
- Restricted formularies

### Condition-Related

- Lack of symptoms
- Severity of symptoms
- Depression
- Psychotic disorders

### Therapy-Related

- Complexity of the medication regimen
- Duration of therapy
- Frequent changes
- Actual or perceived side effects

### Patient-Related

- Visual, hearing, cognitive impairment
- Knowledge about disease
- Perceived risk/susceptibility to disease
- Perceived benefit of treatment
- Motivation and confidence

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# Addressing Barriers to Adherence



- Limited language proficiency
  - Know pharmacies that have interpreters and those that can print medication labels in other languages
  - Automatic refill programs and delivery services
- Low health literacy
  - Provide continued education on disease state and medication therapies in a way patients can understand
- Lack of health insurance
  - Utilize patient assistance programs (PAP) and ADAP programs
- Medication costs
  - Develop good relationships with local insurance companies (Medicaid) and pharmacies
  - Know resources to use for RX costs (copay cards, assistance programs, pharmacy programs)

# Addressing Barriers to Adherence



- Lack of care continuity
  - Function as the liaison between patient, prescriber, and pharmacy
  - Improve health literacy
- Complexity of the medication regimen
  - Reduce pill burden
  - Utilize combination products
- Duration of therapy
  - D/C prophylaxis medications
- Frequent changes
  - Maximize therapeutic options
- Actual or perceived side effects
  - Discuss ways to manage side effects

# Addressing Barriers to Adherence



- Knowledge about disease
  - Education, education, education!
- Perceived risk/susceptibility to disease
  - Education, education, education!
- Perceived benefit of treatment
  - Education, education, education!
- Motivation and confidence
  - Positive feedback, motivational interviewing, support system

# Viral Suppression Trends (2014-2019)



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ECMC Viral Suppression Rates (2014-2019)						
Year	2014	2015	2016	2017	2018	2019
Number of Patients Virally Suppressed	937	921	890	850	600	640
Total Number of Patients	1250	1251	1129	985	679	708
Total Percentage	75%	74%	79%	86%	88%	90%

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ECMC Viral Suppression Rates (2014-2019)						
Year	2014	2015	2016	2017	2018	2019
Number of Patients Virally Suppressed	937	921	890	850	<b>600</b>	<b>640</b>
Total Number of Patients	1250	1251	1129	985	<b>679</b>	<b>708</b>
Total Percentage	75%	74%	79%	86%	88%	90%

# Perks of Clinical Pharmacists



## Pharmacists are the most accessible and frequently visited members of the healthcare team

- Able to spend more time one on one with patients to address medication adherence barriers
- Perform medication reconciliation and have continued monitoring to prevent admissions and re-admissions
- Easily assist patients with side effect management
- Provide medication and disease state counseling
- Offer patient and provider support



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# Questions?



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