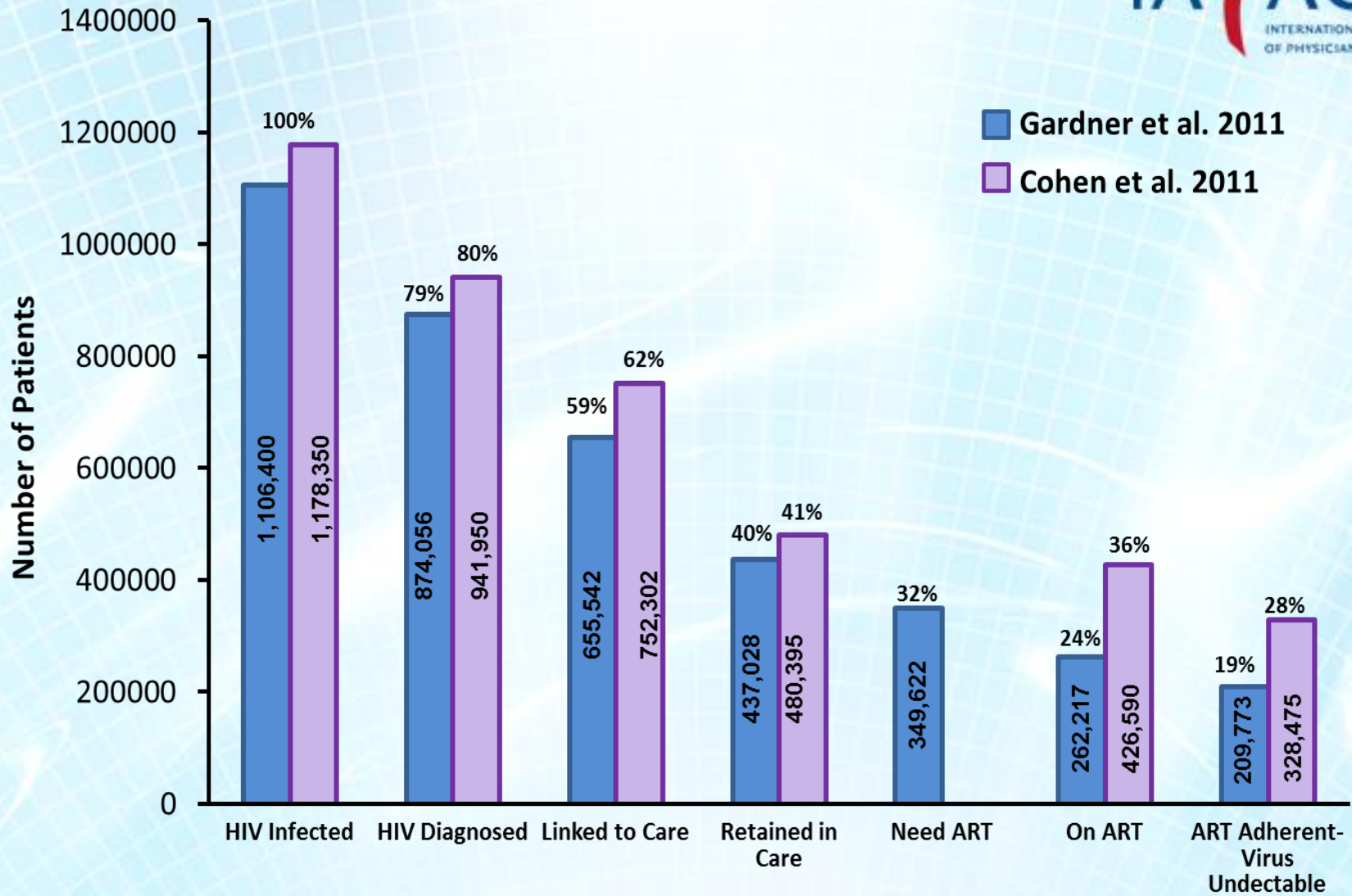




# **ENTRY INTO AND RETENTION IN CARE AND MONITORING ANTIRETROVIRAL ADHERENCE FOR PERSONS WITH HIV**

**Michael J. Mugavero, MD, MHSc  
University of Alabama at Birmingham**

Guidelines Developed by a Panel Convened by the  
International Association of Physicians in AIDS Care



# ENTRY INTO AND RETENTION IN CARE

- Associations between entry into and retention in HIV medical care and both individual health outcomes and HIV transmission have been well established in retrospective, prospective and mathematical modeling studies
- Individual-level monitoring of entry and retention in care is essential to developing and evaluating interventions

## RECOMMENDATIONS: ENTRY INTO/RETENTION IN CARE

- Systematic monitoring of successful entry into HIV care is recommended for all individuals diagnosed with HIV (**IIA**)
- Systematic monitoring of retention in HIV care is recommended for all patients (**IIA**)
- Brief, strengths-based case management for individuals with a new HIV diagnosis is recommended (**IIB**)
- Intensive outreach for individuals not engaged in medical care within 6 months of a new HIV diagnosis may be considered (**IIIC**)
- Use of peer or paraprofessional patient navigators may be considered (**IIIC**)

**Systematic monitoring of successful entry into HIV care is recommended for all individuals diagnosed with HIV (IIA)**

**Systematic monitoring of retention in HIV care is recommended for all patients (IIA)**

- Studies have shown significant correlations between methods of monitoring linkage and retention in care with HIV biomarker and clinical outcomes
- Public health surveillance and medical clinic data are demonstrated methods for monitoring linkage and retention

# PRACTICAL APPLICATIONS\*: MONITORING ENTRY INTO/RETENTION IN CARE

- Integration of multiple data sources, including surveillance data, administrative databases, and medical clinic records, may enhance monitoring of initial entry into and retention in HIV care.
- Many retention measures (for example, gaps in care, and visits per interval of time) and data sources (for example, surveillance, medical records, and administrative databases) have been used – tailor to local context.

\*Practical applications of A-level recommendations

# Monitoring HIV Care in the United States

## Indicators and Data Systems

**INSTITUTE OF MEDICINE**  
OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

**A number of obstacles prevent people with HIV from experiencing optimal health, including late diagnosis, delayed access to care, breaks in care, delayed prescription and intermittent use of life-saving antiretroviral therapy, untreated mental health and substance use disorders, and unmet basic needs.**

**Table 1: Core Indicators for Clinical HIV Care**

**Proportion of people newly diagnosed with HIV with a CD4+ cell count  $>200$  cells/mm<sup>3</sup> and without a clinical diagnosis of AIDS**

**Rationale:** Improve health outcomes by reducing the number of people living with HIV/AIDS (PLWHA) with late diagnosis.

**Proportion of people newly diagnosed with HIV who are linked to clinical care for HIV within three months of diagnosis**

**Rationale:** Timely linkage to care improves individual health outcomes and reduces transmission of the virus to others.

**Proportion of people with diagnosed HIV infection who are in continuous care (two or more visits for routine HIV medical care in the preceding 12 months at least three months apart)**

**Rationale:** Continuous HIV care results in better outcomes, including decreased mortality, and reduced transmission of the virus to others.

**Proportion of people with diagnosed HIV infection who received two or more CD4 tests in the preceding 12 months**

**Rationale:** Regular CD4 testing permits providers to monitor individuals' immune function, determine when to start antiretroviral therapy (ART), and assess the need for prophylaxis for opportunistic infections.

**Proportion of people with diagnosed HIV infection who received two or more viral load tests in the preceding 12 months**

**Rationale:** Regular viral load (plasma HIV RNA) testing is important for monitoring clinical progression of the disease and therapeutic response in individuals on ART.

**Proportion of people with diagnosed HIV infection in continuous care for 12 or more months and with a CD4+ cell count  $\geq 350$  cells/mm<sup>3</sup>**

**Rationale:** Achieving and maintaining a CD4+ cell count  $\geq 350$  cells/mm<sup>3</sup> reduces the risk of complicating opportunistic infections and cancers.

**Proportion of people with diagnosed HIV infection and a measured CD4+ cell count  $<500$  cells/mm<sup>3</sup> who are not on ART**

**Rationale:** Appropriate initiation of ART improves individual health outcomes and reduces transmission of the virus to others.

**Proportion of people with diagnosed HIV infection who have been on ART for 12 or more months and have a viral load below the level of detection**

**Rationale:** The goal of ART is durable virologic suppression, which improves health outcomes and reduces transmission of the virus.

**All cause mortality rate among people diagnosed with HIV infection**

**Rationale:** Mortality rate is the ultimate outcome measure for people diagnosed with HIV infection. Mortality among PLWHA should be inversely related to the quality of overall care delivered.

## Brief, strengths-based case management for individuals with a new HIV diagnosis is recommended (IIB)

- CDC ARTAS: Multi-site RCT to test a case management (CM) intervention vs. SOC to improve linkage to care
  - Empowerment & self efficacy
  - Asks clients to identify internal strengths & assets
  - Up to 5 CM contacts allowed in 90 days
- 78% linkage to care w/in 6 months in CM group vs. 60% in SOC group (P<0.01)



**Intensive outreach for individuals not engaged in medical care within 6 months of a new diagnosis may be considered (IIC)**

**Use of peer or paraprofessional patient navigators may be considered (IIC)**

- Recommendations based upon HRSA SPNS outreach initiative
  - A series of observational studies with comparators that measured behavioral and biological outcomes
- Intensive outreach improved retention in care and HIV-1 RNA suppression in patients underserved by health care system
- Patient navigation associated with increased retention in care from 64% to 79% and 50% increase in HIV-1 RNA suppression

## FUTURE RESEARCH RECOMMENDATIONS : ENTRY INTO/RETENTION IN CARE

- Comparative evaluation of monitoring strategies in conjunction with intervention studies
- Comparison of retention measures with one another
- Operational research to optimize / standardize measurement
- Comparative evaluation of CM in community settings
- Comparative evaluation and cost effectiveness for best practices for implementation of CM interventions
- Comparative evaluation of other intervention approaches: peer support, patient navigation, health literacy, life skills
- Prospective evaluation of pay for performance interventions

# MONITORING ART ADHERENCE

- Monitoring ART adherence is necessary to assess the effect of interventions and also to inform providers of the need to implement interventions
- Methods include self-reports, pharmacy refill data, pill counts, electronic drug monitors (EDMs), and drug concentrations from biological samples; unique strengths and weaknesses
- Regardless of measurement method, adherence varies with time and therefore must be repeatedly assessed

## RECOMMENDATIONS: MONITORING ART ADHERENCE

- Self-reported adherence should be obtained routinely in all patients (**IIA**)
- Pharmacy refill data are recommended for adherence monitoring when medication refills are not automatically sent to patients (**IIB**)
- Drug concentrations in biological samples are not routinely recommended (**IIIC**)
- Pill counts performed by staff or patients are not routinely recommended (**IIIC**)
- Electronic drug monitors (EDMs) are not routinely recommended for clinical use (**IC**)

## **Self-reported adherence should be obtained routinely in all patients (IIA)**

- Self-reported ART adherence consistently associated with HIV-1 RNA levels, although tends to over-estimate adherence
  - Self-reported non-adherence has a high predictive value
  - Ease of implementation supports use in clinical care

## **Pharmacy refill data are recommended for adherence monitoring when medication refills are not automatically sent to patients (IIB)**

- Studies across the globe have demonstrated the validity of pharmacy refill data as an ART adherence measure
  - Medical records, claims data, ad hoc pharmacy contact
  - Interval of refill records use depends on the days' supply

## PRACTICAL APPLICATIONS\*: MONITORING ART ADHERENCE

- Self-reported adherence is less strongly associated with treatment responses than are EDM- or pharmacy-based measures, but relative ease of implementation supports its use in clinical care
- Careful attention must be paid to collecting self-report data in a manner that makes reasonable demands on memory
- Questionnaires should inquire only about specific doses taken over a short time interval (e.g., in the previous week) and about global measures of adherence over a longer time interval (e.g. in the previous month)

\*Practical applications of A-level recommendations

## **Drug concentrations in biological samples are not routinely recommended (IIIC)**

- Concentration of ARVs in various biological samples assessed as an adherence measure; relatively few analyses associated with clinical outcomes and results inconsistent

## **Pill counts performed by staff or patients are not routinely recommended (IIIC)**

- Association between pills counts and biological outcomes seen in some studies, but not in all
- Clinic-based pill counts are susceptible to pill dumping

## **Electronic drug monitors (EDMs) are not routinely recommended for clinical use (IC)**

- Better associated with HIV-1 RNA than are other methods
- Technologies currently impractical outside of research setting

## FUTURE RESEARCH RECOMMENDATIONS : MONITORING ART ADHERENCE

- Define duration of adherence period for longitudinal measures that provides most clinically useful information
- Advance EDM technology to reduce cost and enhance real-time monitoring
- New methods for drug measurement in biological samples
- Methodological research to optimize monitoring validity
- Operational research to optimize / standardize measurement
- Improve monitoring methods for non-solid formulations