



**“Disease Management Programs
HIV/AIDS”**

Disease Management Colloquium

Philadelphia, PA

22 June 05

Scott C. Howell, DO, MPH&TM, CPE

AIDS Healthcare Foundation Bureau Chief, Southeast and Caribbean Regions



AIDS Healthcare Foundation RECAP: Managing HIV/AIDS Populations in State or Federal Programs

- FULL Risk-Bearing Medicaid MCO in California for AIDS diagnosis
 - Successful 10 year history of shared savings
 - Never had to use reinsurance
 - Expertise in utilization review
 - Successful inspections by MediCal and CMS-Medicare
- Disease Management Florida HIV/AIDS
 - **10,000** covered lives in all 67 Counties
 - Saved **\$21 Million** net in 65 Counties from 1 July 99 through 1 Nov 01
 - SSI, TANF and PAC Waiver

Depth of Medical HIV/AIDS Expertise

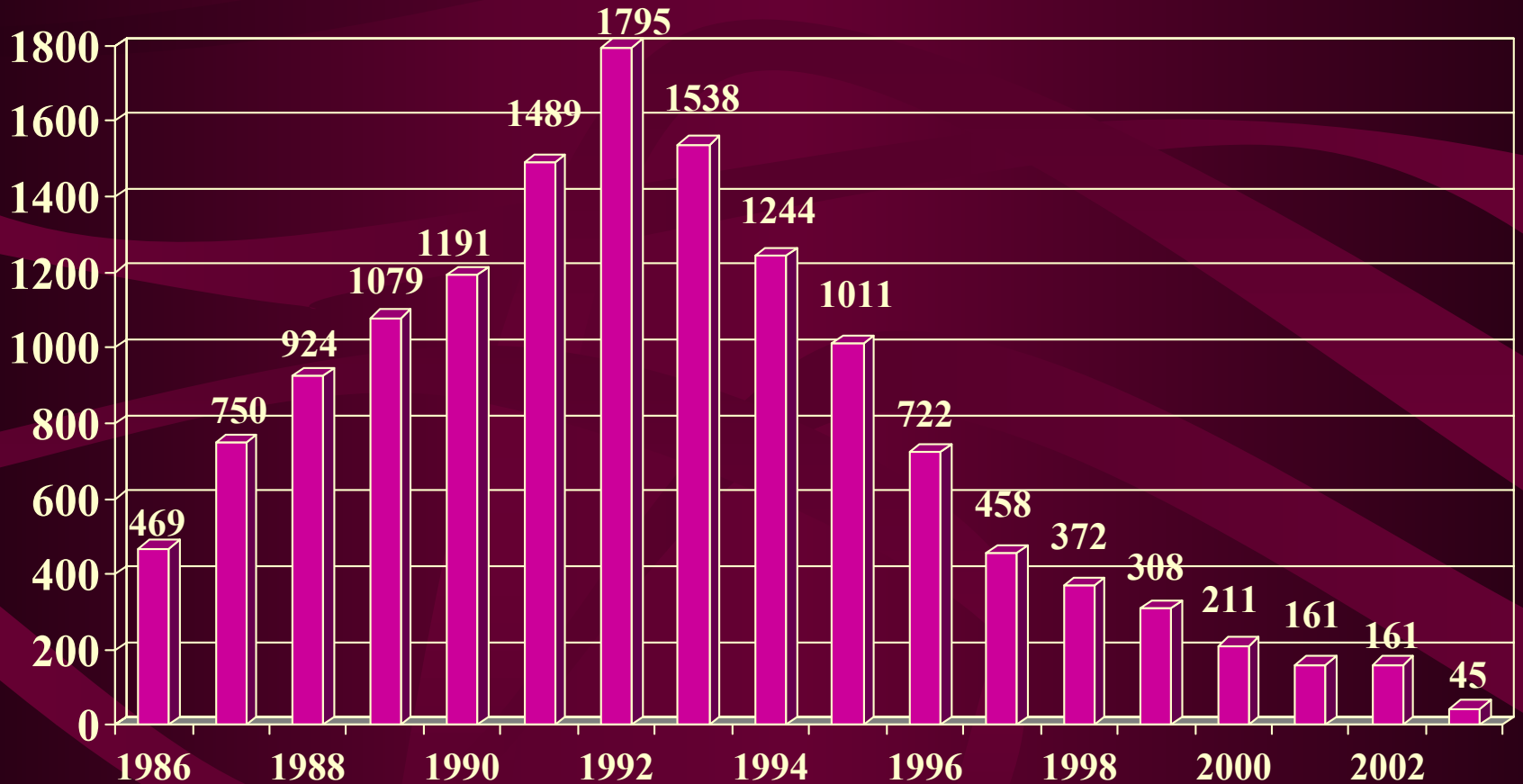
- 14 Domestic Medical Clinics
 - 30 Board Certified Physicians
 - 20 certified AAHIVM physicians
- 13 International Clinics: Uganda, South Africa, Zambia, Honduras, Haiti
- Medical Advisory Board from Top Academic Institutions: UCLA, USC, U of Miami, etc.....
- Nine Pharmacies with specialized HIV pharmacists
 - 16,000 Rx per month; 340(b) program
- Nationally Recognized Adherence Program

Paradigm Shift in HIV/AIDS

The initiation of Protease Inhibitors in 1995 transformed treatment modalities from **ACUTE** treatment of inpatient opportunistic infections to **CHRONIC** outpatient viral suppression

Pennsylvania Annual Incidence 1986-2003

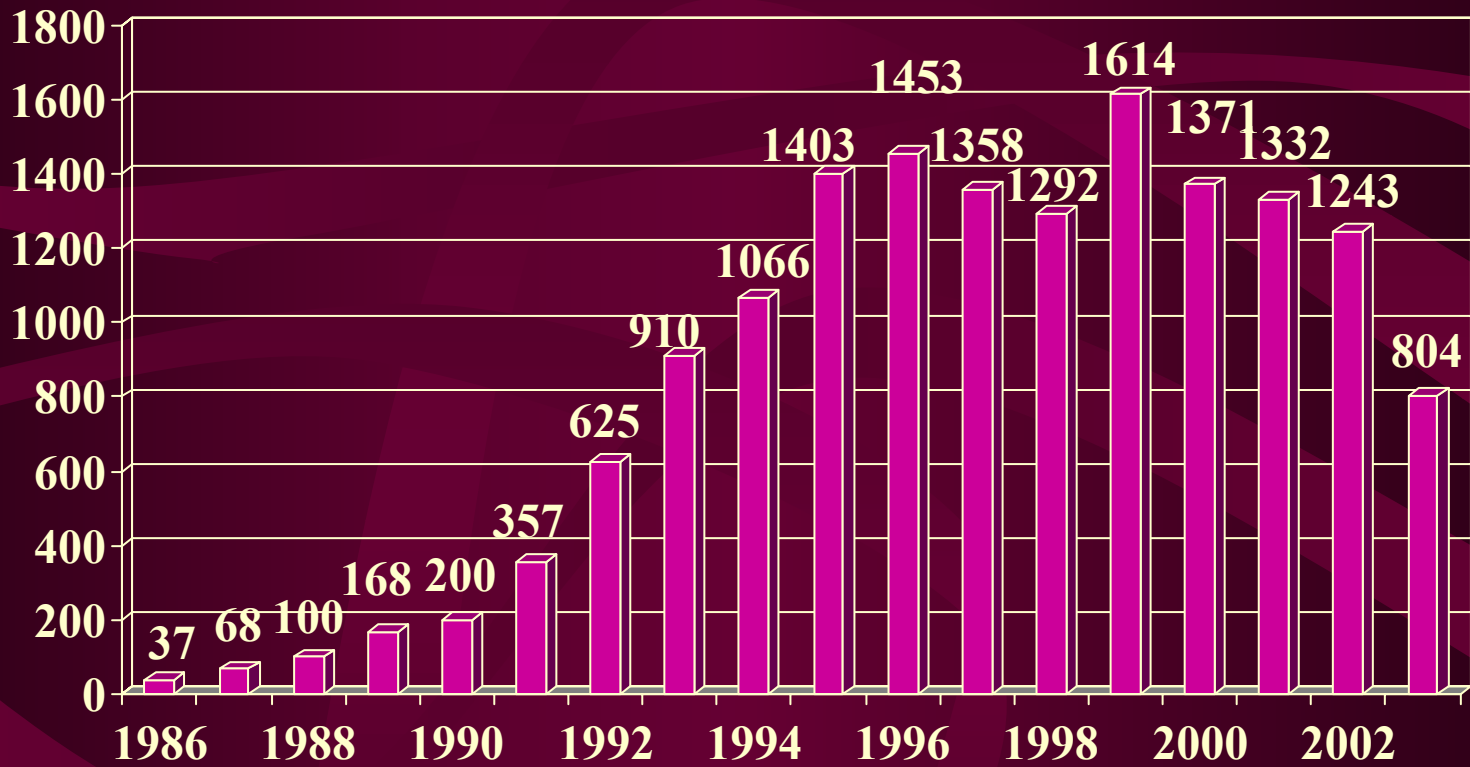
Current AIDS Mortality: Year of Diagnosis



Death Rate by Year for AIDS Diagnosis

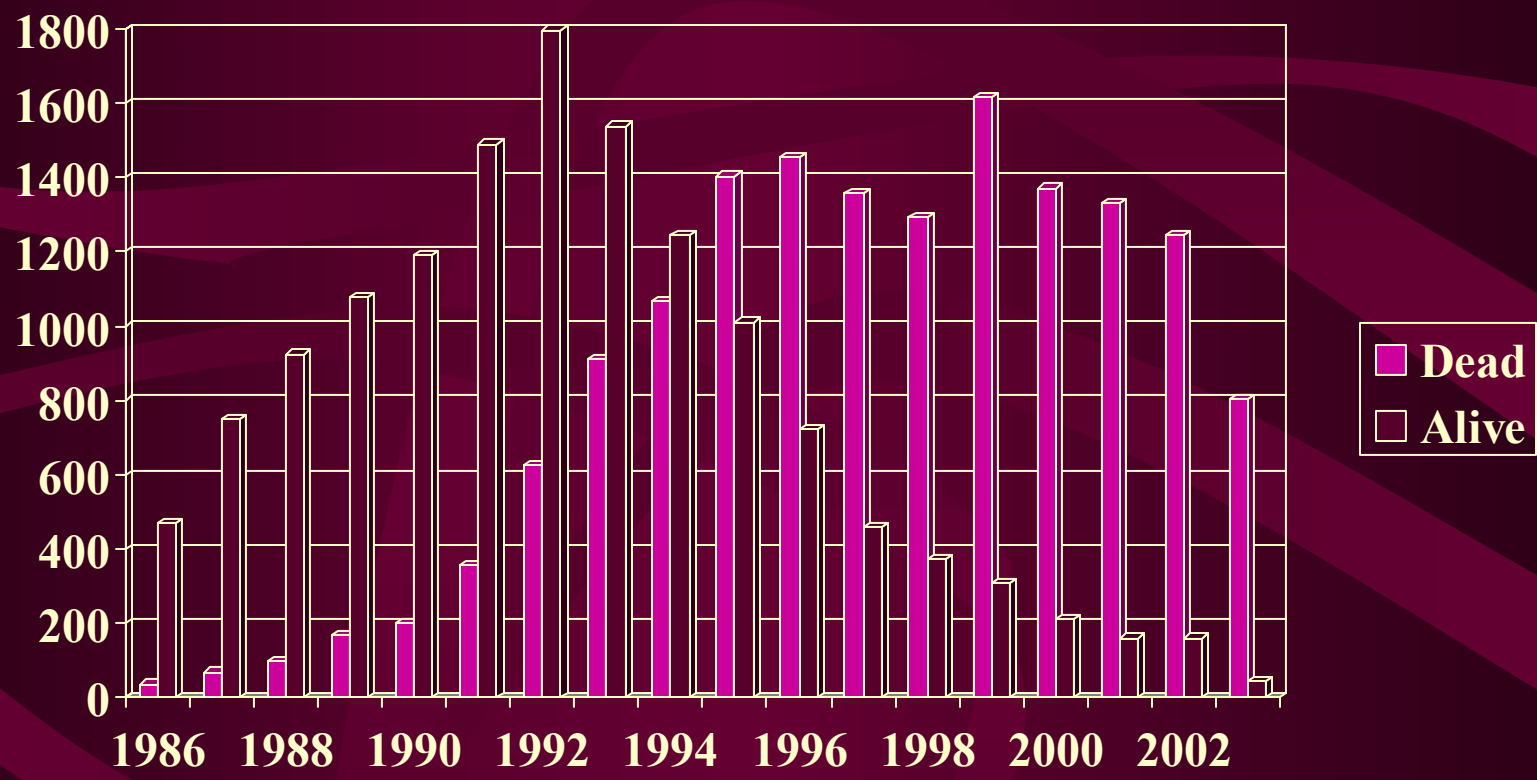
Pennsylvania Annual Incidence 1986-2003

Current AIDS Living: Year of Diagnosis



Alive Rate by Year for AIDS Diagnosis

Pennsylvania Annual Incidence 1986-2003
Current AIDS Mortality and Living: Year of
Diagnosis



Combined Dead and Alive AIDS Cases by Year

Source: Pennsylvania Department of Health; HIV/AIDS Surveillance Biannual Summary; 31 Dec 03

HIV/AIDS Disease Management?

HIV/AIDS is UNLIKE the other standard disease management illnesses of congestive heart failure, asthma, diabetes mellitus or hemophilia



HIV/AIDS Disease Management?

HIV/AIDS is still a **PUBLIC HEALTH** concern with potential sexual and blood-borne transmission.

Indirect Benefits

- States that initiate HIV/AIDS disease management programs gain in not only optimizing individual care but also **INDIRECTLY** through population dynamics by reducing HIV, Hepatitis B, STD and tuberculosis transmissions

HIV/AIDS Disease Management?

- Why would HIV/AIDS be considered for Disease Management or Capitation?
 - Long-Term Progressive Disease
 - Effective Treatment with Antiretrovirals
 - Problematic Adherence to Medications
 - Extremely Expensive Treatment Failures for Salvage Therapies and Hospitalizations

Virologic Failure Definition

- Virologic Failure:
 - Confirmed HIV RNA level >400 copies/ml after 24 weeks, > 50 copies/ml after 48 weeks or a repeated HIV RNA level > 400 copies/ml after prior suppression of viremia below 400 copies/ml

Treatment Naïve Recommendations

| <u>Preferred Regimens</u> | Regimens | No. of Pills |
|------------------------------------|--|------------------|
| NNRTI -based | Sustiva + (3TC/FTC) + (AZT/TFV) | 2-3 pills |
| PI-based | Kaletra + (3TC/FTC) + AZT | 8-9 pills |
| <u>Alternative Regimens</u> | | |
| NNRTI-based | Sustiva + (3TC/FTC) + (ABC/DDI/D4T) | 2-4 pills |
| | Viramune + (3TC/FTC) + AZT/D4T/DDI/ABC/TFV) | 3-6 pills |
| PI-based | Reyataz +(3TC/FTC) + (AZT/D4T/ABC/TFV) or (TFV and RTV) | 3-6 pills |
| | Lexiva + (3TC/FTC) + (AZT/D4T/ABC/TFV/DDI) | 5-8 pills |
| | Lexiva/Norvir + (3TC/FTC) + (AZT/D4T/ABC/TFV/DDI) | 5-8 pills |
| | Crixivan/Norvir + (3TC/FTC) + (AZT/D4T/ABC/TFV/DDI) | 7-12 pills |
| | Kaletra + (3TC/FTC) + (AZT/D4T/ABC/TFV/DDI) | 7-10 pills |
| | Viracept + (3TC/FTC) + (AZT/D4T/ABC/TFV/DDI) | 5-8 pills |
| | Fortovase/Norvir + (3TC/FTC) + (AZT/D4T/ABC/TFV/DDI) | 13-16 pills |
| 3 NRTI-based | ABC +AZT +3TC (only when preferred or alternative can't be used) | |

Treatment Goals

- Reduce HIV-related morbidity and mortality
- Improve quality of life
- Restore and preserve immunological function
- Maximally and durably suppress viral load

Review of Preferred Regimens

- NNRTI-Based
 - Viread/Emtriva/Sustiva or Combivir/Sustiva
- Protease Inhibitor-Based
 - Kaletra/Combivir

NNRTI-Based Regiments

- Gilead Sciences Study 934
 - Preliminary 48 week data of the Phase III multicenter open label 96 week clinical trial
 - Compared two treatment preferred regiments:

Viread/Emtriva/Sustiva

Verse

Combivir/Sustiva

Analysis of n=487 patients

End point TLOVR: Time to Loss of Virologic Response algorithm

Viral Load of > 400 copies/ml

84% with Undetectable Viral Loads < 400 copies/ml 48 weeks

Protease Inhibitor-Based Regiments

- Kaletra Containing Regiments
 - Study M98-863 compared Kaletra to Viracept with 2 NRTIs in 653 treatment naïve people
 - **60 weeks data demonstrates 64%** on Kaletra have viral loads < 50 copies/ml
 - Study M97-720 Kaletra dosing equivalence of 100 treatment naïve people
 - **96 weeks data showed 78%** had viral loads < 50 copies/ml
 - After 4 years 70% had viral loads < 50 copies/ml

What Does all Mean?

- The first naïve treatment regiment is the best for maximal and durable suppression.
- The treatment regiments today in CLINICAL TRIALS is at best 84% to < 400 copies/ml

Outside of clinical trials with barriers of social factors, socio-economic conditions, stigma, and medication adverse reactions the reality of suppression is **40-50%**

Barriers to Treatment

- Social Stigma
 - Program that integrates into the different AIDS Service Organizations (ASOs)
 - Integrate into social service organizations
 - Integrate with Ryan White programs and ADAP pharmacies
 - Transitions into programs without losing interruptions of antiretrovirals

Florida Medicaid Program

| | |
|----------------------|---|
| Budget | \$8.8 billion FY 00-01 \$15 billion FY 05-06 |
| Expenditures | 41 st in nation per capita expenditures |
| Eligibles | 2.1 million 4 th largest Medicaid population in US |
| Providers/Plans | 81,000 FFS Providers 11 Medicaid HMOs |
| Managed Care Systems | <ul style="list-style-type: none"> •PCCM 39% •HMO 60% •PSN 1% |
| Claims | <ul style="list-style-type: none"> •116 millions claims annually •450,000 daily |

Florida Medicaid DM HIV/AIDS Current Perspective

- Why HIV/AIDS DM in Florida?
 - 95, 141 Floridians living with HIV/AIDS
(December 2003, Florida Department of Health)
 - 22,191 Medicaid Recipients are living with HIV/AIDS
(June 2004, AHCA)

Florida Medicaid DM Initial Objectives

- Provide and test disease management models
- Encourage the organization and delivery of services resulting :
 - Better Educated Consumers
 - Promoting Best Practices
 - Improved Care
 - Improved Health Outcomes
 - Reduced Inpatient Hospitalization
 - Reduced Emergency Room Visits
 - Lower Total Costs

Florida Medicaid DM HIV/AIDS Current Perspective

- Medicaid Service Provision
 - Medicaid HMO (no PAC)
 - Fee for Service
 - Primary Care Case Management (MediPass)
 - Disease Management
 - Home and Community Based Waiver (Project AIDS Care –PAC)

Florida Medicaid DM HIV/AIDS Successes

- Enrollment
 - “On the ground” Nurse Care Manager presence
 - Face to Face Initial Assessment
- Barriers:
 - Stigma of Illness
 - Program Branding
 - Beneficiary Contact Information
 - “Churn”-loss of Medicaid eligibility

Florida Medicaid DM HIV/AIDS Successes

- Data
 - Identification of Outliers
 - Implementation of Prior Authorization for Certain Drugs
- Clinical Practice
 - Reaching Rural Providers
 - Reaching Providers with small HIV/AIDS practice
- Outcomes
 - Decreased Inpatient LOS
 - Decreases Medical Claims Costs

What Does all Mean?

HIV/AIDS disease progression will continue for many and more complex treatment regimens follow along with morbidity of opportunistic infections associated with immune-destruction.

Disease Management or capitation is essential to eliminate these barriers to attain maximum and durable viral suppression