

# Office of AIDS Programs and Policy

Medical Advisory Committee

April 30, 2010

9:00-11:30am



# nPEP Pilot Program (P-QUAD) Status Update

OAPP Medical Advisory Committee  
April 30, 2010

Jennifer N. Sayles, MD, MPH  
Medical Director  
Office of AIDS Programs and Policy



# P-QUAD nPEP Inclusion Criteria

## (All must be satisfied)

1. 18 yrs of age and able to provide consent
2. High-risk exposure (unprotected or with failed condom):
  - Receptive/Insertive Anal Intercourse
  - Receptive/Insertive Vaginal Intercourse
  - Receptive Oral Intercourse w/ejaculation with HIV+ source
  - Sharing intravascular injection drug works
3. High-risk source (one or more):
  - Known HIV+, MSM, MSM/W, IDU, CSW, Sexual perpetrator, History of incarceration, From an endemic country (prevalence >1%), Partner of one of the above
4. Exposure within 72-hrs of presentation
5. Not known to be HIV+
6. No countermanding concomitant medications or allergies



# P-QUAD Medication Regimens

- Standard Regimen:
  - Truvada – for high-risk exposures (100 doses)
  - Combivir – for intolerance to Truvada (50 doses)
- Expanded Regimen:
  - Kaletra – for highest-risk exposures or suspected source drug resistance, add to the above medication administration (100 doses)
- Additional drug procurement:
  - Raltegravir 50 doses, requesting additional 100 doses of Truvada and Kaletra



# Clinical and Laboratory Evaluations

	Baseline (Day 0)	Week 2 Visit (Day 10-14)	Week 4-6 Visit	Week 12 Visit	Week 24 Visit
Meds Dispensed	X	X			
HIV ELISA <sup>c</sup>	X		X	X	X
Urine GC/CT Rectal GC/CT Pharynx GC	X				
Serum RPR	X			X	
Urine HCG <sup>a</sup>	X	X <sup>b</sup>	X <sup>b</sup>	X <sup>b</sup>	X <sup>b</sup>
HBsAg	X				
Cr, LFTs, CBC	X	X <sup>b</sup>			
HIV RNA					
HIV Genotype					
Stored Plasma/PBMCs <sup>d</sup>	X		X	X	X
Adherence Cnsl	X	X			
Drug and Alc Assess	X				
Risk Assess	X		X	X	X
Risk Red (Standard)	X	X			
Behavioral Program (Expanded)	X				

<sup>a</sup>Females of childbearing potential only

<sup>b</sup>If clinical signs and symptoms direct, not routine

<sup>c</sup>Positive or indeterminate rapid HIV ELISA testing will be confirmed with a serum Western Blot

<sup>d</sup>Plasma and PBMCs will be drawn and stored at indicated time points. If seroconversion to HIV occurs, these samples will be run for HIV RNA (viral load) and genotyping



# Clinical Demonstration Sites

## **LA Gay and Lesbian Center**

1625 North Schrader Blvd.

Los Angeles, CA

323.860.5880

## **MLK/MACC – OASIS Clinic**

1807 East 120<sup>th</sup> Street

Los Angeles, CA

310.668.5131



# P-QUAD Enrollment to Date

- LAGLC

- Project launched March 2, 2010

Enrolled: N = 15

- N = 15 received expanded regimen Truvada/Kaletra
- N = 10 completed 28 day regimen (5 are currently on regimen)

- OASIS

- Project launched April 15, 2010

Enrolled: N = 1 (4/28/2010)





COUNTY OF LOS ANGELES  
**Public Health**



# Medical Care Coordination An Overview

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# What is Medical Care Coordination?

The Medical Care Coordination (MCC) model is a multi-disciplinary team approach that integrates medical and non-medical case management.

MCC team members are co-located at the client's medical facility, in order to better facilitate clients' access and adherence to HIV medical care.



# Rationale

- To promote linkage to and retention in medical care
- To standardize assessment and referral
- To identify and remove barriers to treatment adherence
- To improve health outcomes
- To reduce duplication of services
- To foster a medical and a non-medical home for clients



# Ryan White Utilization in Year 18

**18,866** Ryan White clients

- **78%** (14,723) receive medical care
- **8%** (1,590) receive medical case management
- **24%** (4,485) receive psycho-social case management; of these
  - **69%** (**3,084**) access Ryan White medical care



# Ryan White Utilization in Year 18

- **1,781** new clients registered in CW
  - 1,184 entered medical care
- **~2,000** former patients didn't access Ryan White medical services in Yr 18



# Program Goals

- Streamline care coordination to improve HIV+ patients':
  - Access to medical care
  - Adherence to care and treatment
  - Health outcomes
- Eliminate duplication of services
- Standardize services across sites
- Reduce HIV transmission



# Target Population for MCC

- HIV+ clients who:
  - Are not in medical care
    - Recently diagnosed <6 months
  - Have fallen out of care
  - Are currently in care and having trouble adhering to care plan
  - Are adherent but have poor health status



# Program Design

- Screening
- Assessment / Acuity
  - Medical service needs
  - Non-medical service needs
- Integrated care plan
- Multi-disciplinary case conferencing
  - Co-located MCC team
- Follow-up and reassessment





# MCC Structure

## Client Entry/Engagement into Care

PS

HCT

CBO

Clinic

STD



## Screening and Triage

Medical CM

Non-Medical CM



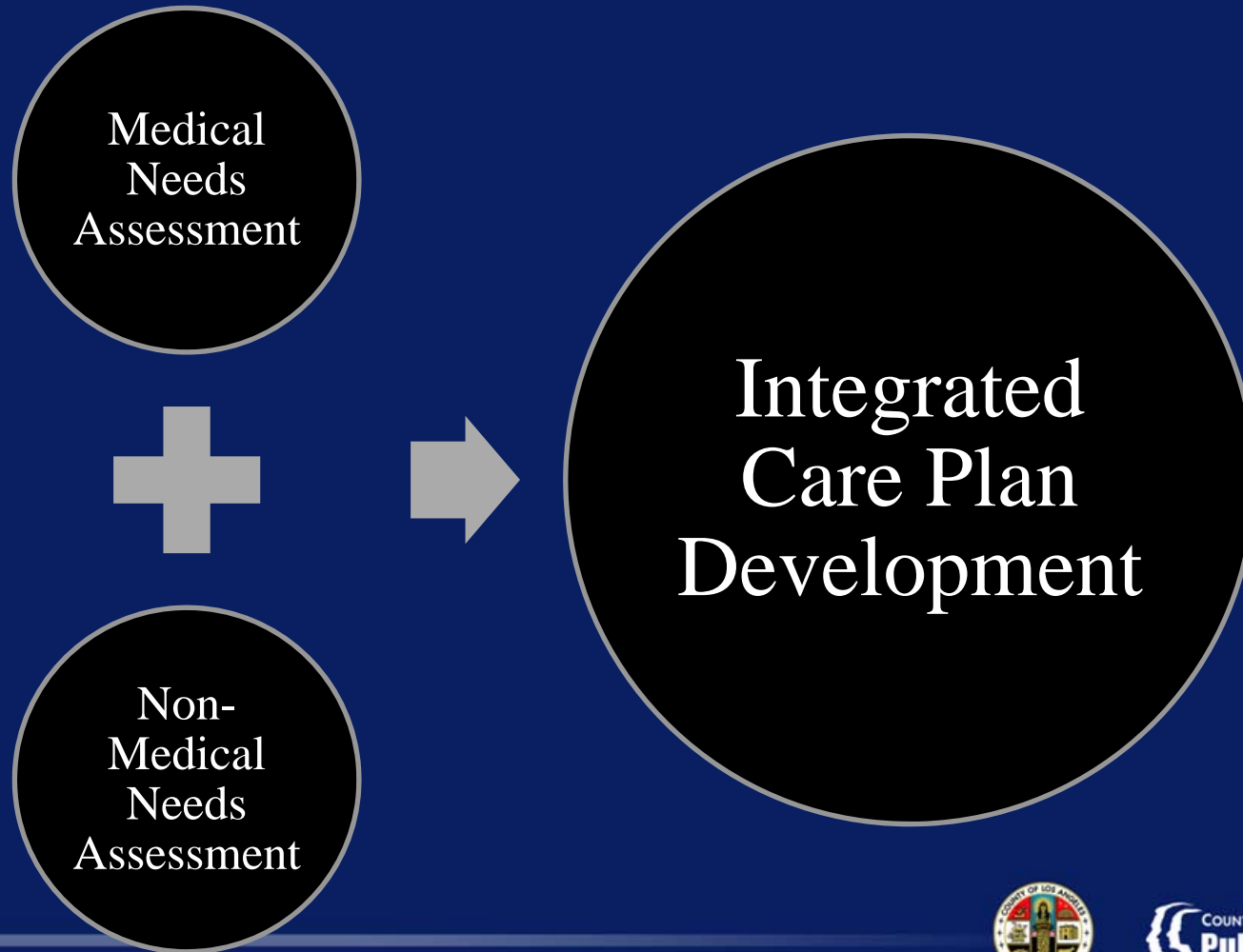
## Comprehensive Assessment of Needs

Acuity Determination

Case Conference



# Integrated Care Plan



# Implementation



## Non Medical

- Risk Reduction Counseling
- Housing
- Substance Abuse Treatment
- Public Benefits
- Disclosure
- Mental Health



## Medical

- Co Infections
- Tx Side Effects
- Nutrition
- Adherence
- Patient Education

Multidisciplinary Case Conference/ Collaboration



# Discussion

- Are these coordinated services currently offered in your clinic?
- How will this model be integrated into your clinic?
- Who will perform functions?
- When will patients be assessed?
- How will data be shared?



# Contact Information

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