

# SAMHSA Hepatitis A and B Vaccine Initiative

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# Objective

Pilot Program to assess the feasibility of providing hepatitis immunization services by substance abuse prevention/treatment settings to individuals at high risk for hepatitis and to evaluate efficacy of vaccination in individuals at-risk for liver disease progression

# Specific Aims

- Establish collaborative agreements to enhance vaccination against hepatitis A and hepatitis B infections for patients at risk for HIV and/or hepatitis C
  - Individuals with co-occurring hepatitis A and/hepatitis B infection risk enhanced liver disease
- Evaluate vaccine distribution and outcome
  - Stratify by program type and demographics

# Substance Abuse Treatment Settings

- Opioid Treatment (Methadone) Programs (25)
- Office based buprenorphine treatment in HIV Primary Care Settings (10)
- CSAT Minority AIDS Initiative Grantees (10-15)
- CSAP Minority SA/HIV/Hep Strategic Prevention Framework (SPF) Grantees (10-15)

# Collaborative Agreements

- Programs with active assessment and management of HIV and HCV
  - hepatitis vaccination protocols/referrals for vaccination
- Establish participation by invitation
  - Letter from CSAT sent Mid November
  - Establish contacts/agreement to participate
  - Collect standard operating procedures

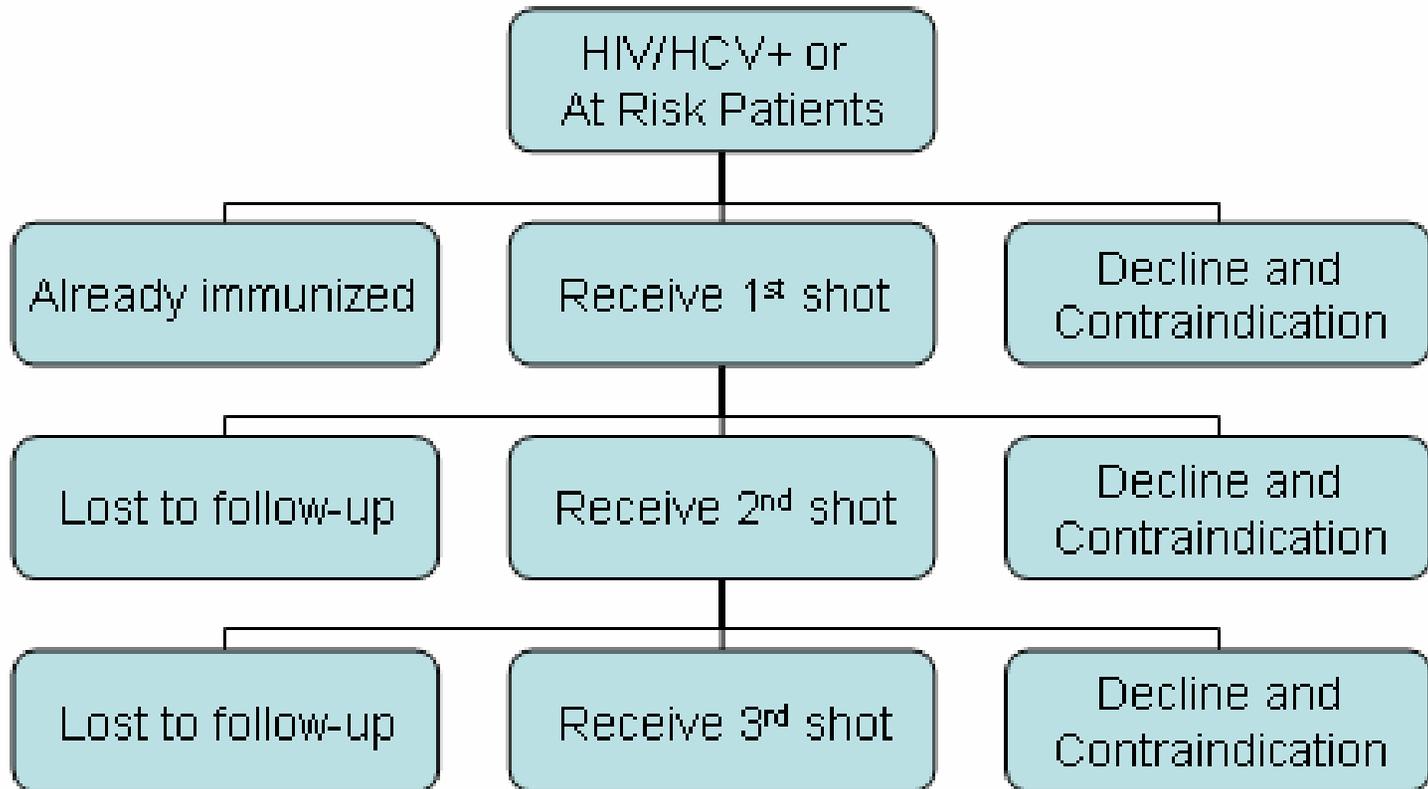
# Contracts

- Vaccine distribution contract
  - Infection Control Consultation Services
  - Hepatitis A/B vaccine (Twinrix ®) to 60 sites
  - Track distribution patterns and utilization
- Evaluation contract
  - Westat
  - Describe use within sites
  - Connect with buprenorphine prescribing clinicians identified within HRSA SPNS

# Evaluation Strategy

- Monitor the status of the vaccine provided to sites
- Describe the characteristics of the sites that delivery the vaccine and the patients that receive it
- Identify the factors that facilitate and/or impede the effective delivery of vaccine service
- No evaluation staff on site, rely on clinician cooperation and administrative contact
- Procedures designed to minimize site burden
- Data collected on all who are offered vaccination
- Data collected by site staff at the time of referral and at time the vaccine is administered

# Evaluation Strategy



# Analysis

- Total potential population: 10,000 – 15,000
  - Average of 200 persons per site
- Stratified Population Groups
  - Demographics
    - Gender, age group, ethnicity, program setting
  - Known Serological and Disease status
    - HIV, HCV, Substance Use Disorder (SUD) diagnosis
- Outcome
  - % in each group completing 1, 2 and 3 shots
  - Safety and adverse event issues reflected in VAERS

# Data Sources

- Site Protocol
- Agreement with SAMHSA
- CSAT project officer interviews with site staff
- N-SSATS
- Initial contact and weekly contact with sites

# Initiative Outcomes

- Establish vaccination work process within different treatment settings
- Describe connectivity between immunization providers (local health departments) and substance abuse prevention and treatment programs

# POINT OF CONTACT

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