

NICK MACCHIONE, FACHE

AGENCY DIRECTOR

HEALTH AND HUMAN SERVICES AGENCY

WILMA J. WOOTEN, M.D., M.P.H.

PUBLIC HEALTH SERVICES

PUBLIC HEALTH OFFICER

3851 ROSECRANS STREET, MAIL STOP P-578

SAN DIEGO HIV PLANNING GROUP (HPG) MEDICAL STANDARDS & EVALUATION COMMITTEE (MSEC) Tuesday, May 09, 2023 4:00 PM County Operations Center (COC) 5560 Overland Ave, San Diego, CA 92123 (Training Room 171)

MEETING PACKET

NOTE: This meeting is audio and video recorded.

Group Charge: Ensure that HIV Primary Care services provided through local Ryan White-funded clinics meet or exceed established HIV clinical practice standards and Public Health Services (PHS) guidelines, assuring availability and access to state-of-the-art medical care for all eligible persons living with HIV (PLWH).

A quorum for this committee is 7

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Medical Standards & Evaluation Committee (MSEC)

When: Tuesday, May 9, 2023 from 4:00 PM – 5:30 PM Where: Training Room 171 (5560 Building)



<u>Address:</u> San Diego County Operations Center (COC) 5560 Overland Avenue San Diego, CA 92123



Parking is free – All visitors parking is longer than the permitted time that is posted; you must park in an unmarked space. There is very limited street parking along Farnham St.

From 163:

- **1.** From 163, exit onto Clairemont Mesa Blvd *Eastbound*
- 2. Turn left onto Overland Ave.

From I-15:

- 1. From 15, exit onto Clairemont Mesa Blvd Westbound
- 2. Turn right onto Ruffin Rd
- 3. Turn left onto Hazard Way

Or

- 1. From 15, exit onto Clairemont Mesa Blvd Westbound
- **2.** Turn right onto Overland Ave

**ATTN:

Please note that directions depicted on given directions to location may not reflect info on the MTS phone application.

Refer to HPG directions and County Operations Center map provided for detailed instructions on how to get to meeting location. Additional resource map available from County Operations Center on **PAGE 4**.





From Ruffin Road:

- **1.** Head north towards Ruffin Road.
- **2.** Turn left on Farnham Street. Access to County Operations Center buildings will be on your right.

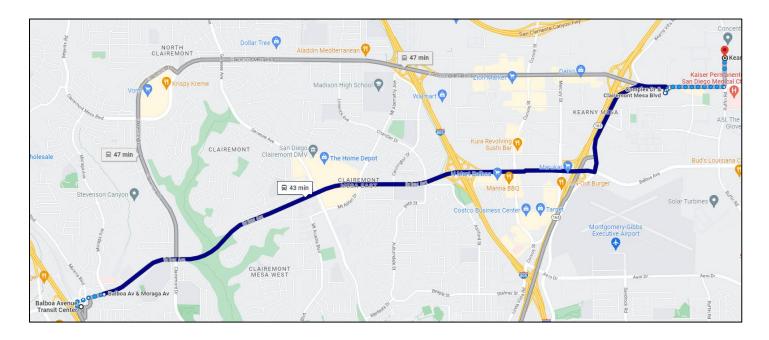
- **2.** Turn left on Hazard Way.
- **3.** Enter through County Operations Center entrance/black gate and head further west.

Access to County Operations Center buildings will be on your left.

From Overland Avenue:

- **1.** Head north on Overland Ave.
- **2.** Enter east through County Operations Center entrance/black gate.
- 3. Turn left on pedestrian walkway. Building 5530 will be on your right.

Full Route from Balboa Ave Transit Center to Overland Ave (if coming off Blue Line trolley):

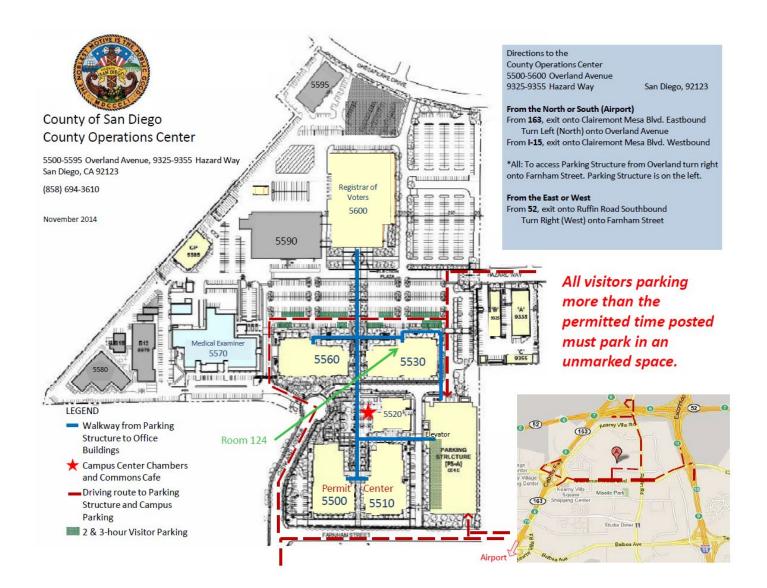


If Using Trolley & Bus:

- 1. Take the **Blue Trolley Line** to the **Balboa Avenue Transit Center**.
- 2. Walk to **Balboa Ave & Moraga Ave** bus stop (about 7-minute walk, 0.3 miles).
- 3. Take Route 27 bus from Balboa Ave & Moraga Ave to Complex Dr & Clairemont Mesa Blvd.
- 4. Head north on Complex Dr.
- **5.** Cross the street and turn right on Clairemont Mesa Blvd (after U.S. Bank Branch on the right).
- 6. Cross the street and turn left onto Overland Ave. and head north.
- 7. Enter east through County Operations Center entrance/black gate.
- 8. Turn left on pedestrian walkway. Building 5530 will be on your right.

ADDITIONAL RESOURCES:

County Operations Center (COC) CAMPUS MAP



County Operations Center (COC) CAMPUS DIRECTORY



5500 Permit Center

Environmental Health and Quality San Diego County Credit Union Public Works Engineering Parks & Recreation Aging & Independence Services 24/7 Library To Go

5510 Permit Center

Planning and Development Services Public Works SanGIS

5520 Campus Center

Campus Center - Chambers Campus Center - Commons

5530

Primary Public Defender Alternate Public Defender County Counsel/Juvenile Dependency Human Resources Sheriff Detention Medical Services Auditor & Controller Revenue & Recovery

5560

County Library Public Administrator Public Guardian Public Conservator Purchasing & Contracting Sheriff Data & Computer Training Scrutity Sovices Security Services

5560 cont.

Property Manager Aging & Independence Services General Services County Fire/EMS

5570

Medical Examiner Environmental Health & Quality - Vector/HIRT Public Health Services - Laboratory

5590 Crime Lab

5595 Sheriff Wireless Services General Services Maintenance

5600 Registrar of Voters County Mail Center Probation

5610 **General Services Fleet**

9325 Agriculture, Weights, & Measures

9335 University of California Cooperative Extension Vital Records Public Health Services



County of San Diego

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PUBLIC HEALTH OFFICER

PUBLIC HEALTH SERVICES 3851 ROSECRANS STREET, MAIL STOP P-578

SAN DIEGO HIV PLANNING GROUP (HPG) Medical Standards and Evaluation Committee (MSEC) Tuesday, May 9, 2023 at 4:00 PM County Operations Center (COC)

5560 Overland Ave, San Diego, CA 92123 (Training Room 171)

To participate remotely via Zoom: <u>https://us06web.zoom.us/j/84265220872?pwd=TGRydGxvcm40dEVIQUhmd0lsWUIZUT09</u> **Call in:** 1-669-444-9171 US Toll **Meeting ID:** 842 6522 0872 **Passcode:** 428631

Language translation services are available upon request at least 96 hours prior to the meeting. Please contact 619-403-8809 or via e-mail at <u>hpg.hhsa@sdcounty.ca.gov</u>.

Group Charge: Ensure that HIV Primary Care services provided through local Ryan White-funded clinics meet or exceed established HIV clinical practice standards and Public Health Services (PHS) guidelines, assuring availability and access to state-of-the-art medical care for all eligible persons living with HIV (PLWH).

Members: Dr. Jeannette Aldous (Co-chair) / Dr. Laura Bamford / Dr. David Grelotti / Yessica Hernandez / Bob Lewis / Mikie Lochner / Shannon Ransom / Dr. Stephen Spector / Lisa Stangl / Dr. Winston Tilghman (Chair) / Karla Quezada-Torres / Dr. Adam Zweig

Quorum: Seven (7)

Agenda:

- 1) Welcome, introductions, moment of silence, comments from the Chair
- 2) Public comment (for members of the public)
- 3) Sharing our concerns (for committee members)
- 4) Approval of the May 9, 2023 meeting agenda
- 5) Approval of the February 14, 2023 meeting minutes
- 6) Old Business:
 - a. **Discussion:** GTZ Community Engagement next steps
 - b. Discussion: Revisions to Ryan White primary care practice guidelines
- 7) New Business:
 - a. **Review:** Executive Report on Compliance with Practice Guidelines 2022
 - b. **Presentation/Discussion:** Doxycycline Post-Exposure Prophylaxis for STD Prevention (Dr. Tilghman)
- 8) Other Updates:
 - a. STD and Mpox Update (Dr. Tilghman)
- 9) Agenda items for future meeting
- 10) Reminder of upcoming meeting date:
 - a. Tuesday, September 12, 2023 at 4:00 PM Location: TBD
- 11) Adjournment



County of San Piego

WORK PLAN

February 14. 2023
•
<u>May 9, 2023</u>
Discuss revisions to Practice Guidelines
Executive Report for review
• Doxycycline post-exposure prophylaxis (doxy-PEP) presentation and
discussion
September 12, 2023
Finalize revised/updated Practice Guidelines
Consider addition of occlusal guards, including hard appliance (D9944)
and soft appliance (D9945) to list of covered oral healthcare services
November 14, 2023
 Consider addition of occlusal guards, including hard appliance (D9944) and soft appliance (D9945) to list of covered oral healthcare services (if not completed in September)



County of San Diego

NICK MACCHIONE, FACHE AGENCY DIRECTOR

HEALTH AND HUMAN SERVICES AGENCY

PUBLIC HEALTH SERVICES 3851 ROSECRANS STREET, MAIL STOP P-578 SAN DIEGO, CA 92110-3134 (619) 531-5800 • FAX (619) 542-4186 WILMA J. WOOTEN, M.D., M.P.H. PUBLIC HEALTH OFFICER

SAN DIEGO HIV PLANNING GROUP MEDICAL STANDARDS & EVALUATION COMMITTEE (MSEC)

Tuesday, February 14, 2023 4:00 PM

Meeting via teleconference (Zoom)

DRAFT MINUTES

Quorum = Seven (7)

<u>Members Present</u>: Dr. Jeannette Aldous (Co-chair) / Dr. Laura Bamford / Dr. David Grelotti / Yessica Hernandez / Mikie Lochner / Karla Quezada-Torres / Shannon Ransom / Dr. Stephen Spector / Lisa Stangl / Dr. Winston Tilghman (Chair)

Members Absent: Bob Lewis / Dr. Stephen Spector / Dr. Adam Zweig

	Agenda Item	Action	Follow-up
1.	Welcome and moment of silence, comments from the Chair	Dr. Winston Tilghman called the meeting to order at 4:15 PM and noted the presence of a quorum. A moment of silence was observed.	
2.	Action: Authorization of Teleconferencing Meeting Option Pursuant to Government Code Section 54953(e)	All votes at the meeting were taken by roll call. Action: Find the HPG has reconsidered the circumstances of the state of emergency and State and local officials have imposed or recommended measures to promote social distancing authorizing teleconferenced meetings pursuant to Government Code section 54953(e). Motion/Second/Count (M/S/C): Lochner/Ransom 7/0 Abstentions: Tilghman Motion carries	
3.	Public Comment	A member of the public expressed concern for in-person meetings and AB 2449. Item was further discussed in item 8 c. on the agenda.	
4.	Sharing our Concerns	None	
5.	Review and approve the February 14, 2023 meeting agenda	Motion: Approve the February 14, 2023 meeting agenda as presented. M/S/C: Lochner/Aldous 8/0	

	Agenda Item	Action	Follow-up
		Abstentions: Tilghman Motion carries	
6.	Review and approve the September 13, 2022 meeting minutes	 Motion: Approve the September 13, 2022 meeting minutes as presented. M/S/C: Grelotti/Bamford 5/0 Abstentions: Aldous, Hernandez, Lochner, Tilghman Motion carries 	
7.	Old Business:		
	a. Review final chart review tool	The final chart review tool, that was used for the review which has already taken place, was reviewed; the tool was included in the meeting packet. The executive report is currently being drafted and it is anticipated that the executive report will be presented at the May 2023 meeting.	
	b. Discussion: GTZ Community Engagement – Next Steps	Suggestions for discussion for the committee to consider at the May 2023 meeting was discussed by Dr. Delores Jacobs: 1. What are the current obstacles for provider systems in terms of being able to meet the requests of some consumers to have non- urgent appointments (e.g., <i>primary care</i> , <i>labs, case management, mental health</i>) coordinated into a single trip to their health center? This is particularly an issue for those with childcare issues, transportation issues, and other challenges in attending multiple appointments. a. <u>Summary of discussion:</u> i. While some patients may prefer bundling their visits or some clinics may prefer to have this done, it may not be in the realm of standards of HIV care to dictate if a medical appointment should or should not be bundled. We can say that bundling appointments are medically acceptable. It is important for providers to realize the psychosocial barriers for consumers to get access to care. Specifying care models is outside of the scope of the mandate and	

Agenda Item	Action	Follow-up
	possibly problematic. Patient preferences are variable. ii. Consumers, particularly those with transportation issues, spend a long time in transportation for appointments that may be	
	relatively short. Also, side effects of medication may be a barrier and may cause consumers to be reluctant to arrive at their appointment. iii. It is important to state items along the lines with "supporting flexible and individualized care plans and access enhancing measures such as telehealth and providing transportation." iv. Some clinics, if they are receiving mostly Medicare, are allowed to bill for only one service per day, so they tend to split up appointments. 2. What is within the purview of MSEC?	
8. New Business:		De sinient te in skude
a. Action: Add occlusal guards, including hard appliance (D9944) and soft appliance (D9945) to list of covered oral healthcare services	Action: Add occlusal guards, including hard appliance (D9944) and soft appliance (D9945) to list of covered oral healthcare services. M/S/C: It was asked if restrictions or a frequency specified and there were none specified. It was recommended to have the expertise of dental professional(s) to provide input.	Recipient to include these two services in the next Needs Assessment to find any unmet needs, gaps, and to do a cost analysis.
	There are times when certain dental procedures are disallowed. If there is an urgent need for a procedure, providers may ask Recipient's office to approve it.	
	If these are appliances that are not covered under other programs, it is possible you will see an increase of people utilizing. Recommendation did not come from dental subcommittee and was based on consumer	

Agenda Item	Action	Follow-up
	and public input and request. It was asked if there was a prior example.	
	The HPG will conduct a needs assessment this year and work with the Recipient's office to get it done. The Recipient's office anticipates completing the needs assessment in the fall of this year.	
	The committee discussed whether dental expertise is needed to determine the need for occlusal guards and recommended seeking input from individual dental providers who were part of the dental task force.	
	Follow up on this agenda item in September/November. It was requested to add this topic to the MSEC Workplan.	
b. Discussion: 2023 meeting dates, priorities, and work	May 9, 2023: Finalize Practice Guidelines, Executive Report for review.	
plan	September 12, 2023/November 14, 2023: Further discussion on adding occlusal guards, including hard appliance (D9944) and soft appliance (D9945) to list of covered oral healthcare services.	
c. Discussion: Discuss committee location for in- person meetings	Future meetings will be in person. This is the last meeting where we will be able to conduct business completely via teleconference.	
	Assembly Bill (AB) 2449: Once the COVID- 19 local emergency lapses, we will be required to meet in person, which means that the committee must have a quorum in person. There is an option for virtual participation by members, however, there are specific criteria for that must be met, and the public must be allowed to participate virtually if desired. All committees are considering meeting locations. Location of March HPG committee meetings were shared to attendees. April committee meetings will take place at the County Operations Center (COC). If there are meetings outside of public spaces, specifically non-County spaces, it required to have County approval which takes about 8 weeks to obtain.	

Agenda Item	Action	Follow-up
	This committee is a body of the HIV Planning Group regardless of how many times the committee meets each year.	
	One item for consideration is that there are several medical providers on this committee so in-person meetings would impact patient care. Many of the providers are located in the Central Region or South Bay. If the group feels we need to change the time, it could change to 5:00 PM - 7:00 PM or $11:30 AM - 1:00 PM$ as examples. Traffic was another item to take into consideration.	
d. Discussion: Committee data requests for 2023	No additional committee data requests given.	
e. Discussion: Revisions to Ryan White primary care practice guidelines	Table to next meeting.	
f. Review and approval of revised committee operational guidelines	Motion: Accept draft recommendations which will be incorporated into main Committee Operating Guidelines document and presented to the Steering Committee.	
	M/S/C: Lochner/Grelotti 8/0 Abstentions: Tilghman Motion carries	
9. Other Updates:		
a. STD and Mpox Update (Dr. Tilghman)	County of San Diego Monthly STD Report is included in the meeting materials packet.	
10. Agenda items for future meeting	Tabled to next meeting.	
11. Reminder of upcoming meeting date:	Date: Tuesday, May 9, 2023 Time: 4:00 PM Location: TBD	
12. Adjournment	5:47 PM	

Practice Guidelines for the Care of Persons Living with HIV/AIDS

Ryan White HIV Treatment Extension Act of 2009

San Diego County

In conjunction with United States (U.S.) Public Health Service (PHS) guidelines and accepted community practices, the San Diego County HIV Planning Group's Medical Standards and Evaluation Group recommends the following practice guidelines for the management of human immunodeficiency virus (HIV) infection in patients enrolled in the Ryan White Primary Care Program of San Diego County.

Antiretroviral therapy (ART) and opportunistic infection (OI) prophylaxis (primary and secondary) are recommended in accordance with the most recent PHS guidelines. Guidelines may have been updated since the versions listed below; current versions are available at https://clinicalinfo.hiv.gov/en/guidelines.

For San Diego County Ryan White Clinics, chart reviews and performance assessments conducted on behalf of the County of San Diego Health and Human Services Agency (HHSA) – Division of Public Health Services – HIV, STD, and Hepatitis Branch (HSHB) will be based upon these guidelines.

A. Guidelines for Staging and Baseline Evaluation (recommended to be completed within the first two visits)

- 1) Complete history, to include at least the following:
 - a. General background:
 - Race/ethnicity
 - Current gender identity
 - Sex assigned at birth
 - Housing status
 - Family history
 - Social history
 - Travel history
 - Country of birth
 - b. Current/lifetime sexual history: (See Appendix A for example)
 - Sexually transmitted infection/disease (STI/STD) history during lifetime and/or last 5 years
 - Relationship status
 - Detailed sexual history
 - Partner(s), including HIV status and history of pre-exposure prophylaxis (PrEP) use
 - Exposure sites anorectal, genital, oropharyngeal
 - Use of condoms
 - c. Current/lifetime substance use history:
 - Injection drug use (IDU), during lifetime and/or last 5 years
 - Non-injection drug use, during lifetime and/or last 5 years
 - Alcohol and/or drug treatment history
 - · Sexual activity under the influence of substances
 - Tobacco use, during lifetime and/or last 5 years
 - d. HIV care history:
 - HIV status, including recent/historical CD4+ T-cell count/HIV-1 viral load
 - Prior and current antiretroviral regimens
 - Resistance test results (if available)
 - Current prophylaxis
 - Prior HIV-related complications
 - e. General medical history:
 - Immunizations

- Hepatitis history
- Tuberculosis (TB) risk <u>http://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/phs/tuberculosis_control_prog</u> <u>ram/SanDiegoRiskAssessment-Adults.pdf</u>
- Reproductive history (persons assigned female at birth), including parity, last menstrual period (LMP), and method of birth control
- Current allergies
- Other current medications
- Significant childhood illnesses
- Surgical history
- Mental health history, past/current mental health conditions, symptoms of depression, and psychiatric medications
- Other medical history
- 2) Review of symptoms and general physical exam, including height, weight, temperature, blood pressure, pulse, respiratory rate, general appearance, skin, head, eyes, ears, nose and throat (HEENT), ophthalmoscopy, chest, heart, lungs, abdomen, rectum, anoscopy (if anorectal symptoms), pelvic (persons assigned female at birth), breasts, genitalia, extremities, lymph nodes, mental status, nervous system including reflexes
- 3) Laboratory tests
 - a. For the current list of recommended labs and periodicity, please refer to <u>PHS Guidelines for</u> <u>Laboratory Testing for Initial Assessment and Monitoring of Patients with HIV Receiving</u> <u>Antiretroviral Therapy.</u>
 - b. STI Testing
 - Should be performed at baseline and at least annually thereafter for sexually active clients, more frequently (i.e., every three to six months) if indicated based upon the client's sexual practices.
 - Syphilis serology
 - Gonorrhea/Chlamydia Perform three-site testing (i.e., urogenital, throat, rectum) using nucleic acid amplification testing (NAAT). If antibiotic-resistant *Neisseria gonorrhoeae* is suspected, obtain *N. gonorrhoeae* culture from all exposure sites.
 - Trichomoniasis Screening with NAAT should be performed annually for persons having vaginal sex.
 - Anal Pap test (optional) See Section G Anal Cancer Screening.
 - Resources:
 - <u>Centers for Disease Control and Prevention (CDC) Recommendations for Providing</u> <u>Quality STD Clinical Services, 2020</u>
 - <u>CDC Interim Guidance for STD Care and Treatment During Disruption of Clinical</u> <u>Services</u>
 - o CDC STD Treatment Guidelines, 2015
 - o Updated CDC Gonorrhea Treatment Recommendations, 2020
 - o <u>CDC Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, 2014</u>
 - c. TB Testing
 - Annual screening in the form of Annual Risk Assessment: <u>http://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/phs/tuberculosis_control_program/SanDiegoRiskAssessment-Adults.pdf</u>
 - Annual screening using purified protein derivative (PPD) or interferon-gamma release assay

 If screening test is positive, the patient should have a chest x-ray.
 - Chest x-ray: At least one should be documented in the medical record if the individual has a history of TB or a positive screening test.
 - d. Viral Hepatitis Testing
 - Hepatitis B screening should be performed by testing for hepatitis B surface antibody (HBsAb), surface antigen (HBsAg), and antibody to core antigen (anti-HBc or HBcAb). Those who are susceptible to infection should be vaccinated against Hepatitis B Virus (HBV) (see Section C – Guidelines for Immunization). Patients who are negative for HBsAg and

HBsAb but positive for anti-HBc should be screened for chronic HBV infection by determination of HBV deoxyribonucleic acid (DNA). Those without evidence of chronic infection should consider vaccination.

https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitisb-virus-infection?view=full

Hepatitis C screening with Hepatitis C Virus (HCV) antibody or, if recent (i.e., within last six months) infection is suspected, the patient has advanced immunodeficiency (CD4 count<100 cells/mm³), or the patient has a history of successfully treated or spontaneously cleared HCV infection, ribonucleic acid (RNA) testing should be performed at baseline and at least annually for persons with ongoing risk factors (e.g., IDU) and sexually active men who have sex with men (MSM). HCV RNA should be ordered for all patients with a positive HCV antibody test to assess for active HCV disease.

https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitisc-virus-infection?view=full

- e. Other Testing:
 - Measles antibody titer All persons with HIV born in 1957 or after should be tested for immunity to measles by measuring antibody titers. The measles, mumps, and rubella (MMR) vaccine should be given to persons with CD4 ≥200 cells/mm³ born in or after 1957 who have not received the vaccine or do not have immunity based on laboratory testing (see Section C – Guidelines for Immunization).
- 4) Appropriate referrals, including but not limited to:
 - Treatment adherence counseling
 - Ryan White dental program (recommended annually)
 - Ophthalmologist if CD4 <50 cells/mm³ (recommended)
 - Case management (if eligible)
 - Medical nutrition therapy
 - Clinical trials
 - · Mental health
 - Substance use treatment
 - Partner services/PrEP if client has not achieved sustained viral suppression

For a list of currently funded Ryan White Service Providers, please visit: HIV/AIDS Care and Services Resources (sandiegocounty.gov)

B. Guidelines for Plasma HIV RNA (i.e., Viral Load) Measurements and CD4 Counts <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/plasma-hiv-1-rna-viral-load-and-</u> cd4-count-monitoring?view=full

- 1) HIV-1 RNA (i.e., Viral Load) should be performed upon entry to care, before initiation of ART (if initiation of ART is deferred after entry to care), and within 2-4 weeks but no later than 8 weeks after ART initiation. After initiation or modification of ART, repeat at 4-8-week intervals until undetectable. Continue to monitor every 3-4 months during the first 2 years of ART, and then frequency can be decreased to every 6 months if the viral load is consistently undetectable for two years and the CD4 is >500 cells/mm³.
- 2) CD4+ T-cell Count (i.e., CD4 Count) should be performed upon entry to care and three months after initiation of ART (every 3-6 months in patients who defer ART). After initiation or modification of ART, repeat every 3-6 months during the first 2 years or if the CD4 count is <300 cells/mm³ or if there is any viremia while on ART. May monitor every 12 months if the patient has consistently been on ART with a suppressed viral load and CD4 count 300-500 cells/mm³. Optional once CD4 is consistently >500cells/mm³ and viral load has been undetectable for >2 years.

C. Guidelines for Immunization

Adult Immunization Schedule by Vaccine and Age Group | CDC Vaccines Indicated for Adults Based on Medical Indications | CDC

- 1) Should be offered as soon as possible after initial evaluation at recommended doses.
- 2) Viral loads should not be measured within three weeks of an immunization.
- 3) Pneumococcus (both types), influenza, tetanus, Hepatitis B (if not immune), Hepatitis A (if not immune), human papillomavirus (HPV), meningococcal

- 4) Influenza vaccine: recommended yearly with trivalent inactivated vaccine (live attenuated vaccine is contraindicated in persons living with HIV or PLWH).
- 5) HPV: Recommended for all PLWH through age 26 years as a three-dose series, regardless of the age at initial vaccination. Vaccination may be considered, based on shared clinical decision-making, for persons aged 27-45 years.

https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a3.htm

- 6) Varicella zoster: Two doses of the Shingrix vaccines should be given to patients over the age of 50 years with CD4 count >200 cells/mm³.
- 7) Hepatitis Vaccines:
 - a. <u>Hepatitis B:</u> Recommended in persons with negative serology or isolated positive core antibody (i.e., negative surface antigen and antibody). Double dosing (i.e., 40μg) of single-antigen three-dose vaccines is recommended to increase seroconversion rates. For those patients who do not seroconvert after the first series, a second series is recommended. If these persons do not seroconvert, they are unlikely to respond to a third series. The safety and efficacy of the two-dose vaccine has not been evaluated in PLWH but is an option if a two-dose regimen is preferred. <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitis-b-virus-infection?view=full</u>
 - b.<u>Hepatitis A</u>: Seroconversion rates are likely related to CD4 counts. The vaccine may be given in persons who are seronegative. However, if there is no response and the CD4 counts are less than 500 cells/mm³, persons can receive a repeat series when CD4 counts are higher.
- 8) Pneumococcal: Both the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPV23) are recommended, with the final dose of PPV23 given at ≥65 years of age and ≥5 years after previous PPV23 doses given before age 65 years. For specific recommendations regarding timing of PCV13 and PPV23 doses, see https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/community-acquired-pneumonia-cap?view=full.
- 9) Meningococcal: Vaccination against serogroups A, C, W, and Y is recommended for all persons living with HIV aged ≥2 years. <u>https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm</u>. Vaccination against serogroup B is recommended for persons aged ≥10 years who are at increased risk for serogroup B meningococcal disease due to certain underlying conditions or a serogroup B outbreak. HIV disease is not one of the underlying conditions for which serogroup B vaccination is recommended. Serogroup B vaccination may be considered for adolescents and young adults aged 16-23 years on the basis of shared decision-making. https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm
- 10) Tetanus vaccines: Recommended every 10 years. Recommend that the next booster contain pertussis booster (Tdap) (make sure the patient has had the pertussis vaccine)
- 11) Live Vaccines (Live attenuated influenza vaccine, Varicella or Zoster vaccine, Vaccinia (small pox), Yellow Fever, Live Oral Polio, Measles*, Typhoid) are contraindicated in persons with severe immunosuppression based on the person's age (per Advisory Committee on Immunization Practices or ACIP): CD4<750 for those younger than 12 months, <500 for those aged 1-5 years, and <200 for those >6 years old.

*The MMR vaccine should be given to persons with CD4 ≥200 cells/mm³ born in or after 1957 who have not received the vaccine or do not have immunity based on laboratory testing.
 12) Booster doses as recommended by CDC guidelines.

D. Treatment:

1) All PLWH should receive ART, regardless of CD4 count, to reduce morbidity and mortality, improve health outcomes, and prevent transmission of HIV to others.

2) Whenever possible, treatment should be initiated immediately (or as soon as possible) after diagnosis.

- a. Same-day treatment should be offered if there are no medical indications to defer therapy (e.g., signs/symptoms of intracranial OI).
- b. If treatment is offered before the results of treatment-naïve genotype are available, an integrase inhibitor-based regimen is recommended.

- 3) All PLWH should be informed that maintaining a plasma HIV RNA (viral load) of <200 copies/mL, including any measurable value below this threshold value, with ART prevents sexual transmission of HIV to their partners. Patients may recognize this concept as Undetectable = Untransmittable or U=U.</p>
- 4) Guidelines on antiretroviral treatment regimens can be found at <u>https://aidsinfo.nih.gov/guidelines.</u>
- 5) At the time of revision, an extended-release, injectable drug regimen (coformulation of cabotegravir and rilpivirine) was approved by the Food and Drug Administration (FDA) to replace the current antiretroviral regimen for patients with viral suppression on a stable ART regimen without history of treatment failure and with no known or suspected resistance to either agent. Long-acting injectable ART may be considered for eligible patients and should be administered according to Department of Health and Human Services guidelines: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hhs-adults-and-adolescents-antiretroviral-guidelines-panel.
- 6) For patients with HBV coinfection, as determined by a positive HBsAg or HBV DNA test result, tenofovir disoproxil fumarate or tenofovir alafenamide, plus either emtricitabine or lamivudine, should be used as part of the ART regimen to treat both HBV and HIV.
- 7) Patients with HCV coinfection should be managed based on the most up-to-date recommendations (<u>http://www.hcvguidelines.org</u>). In general, the goals of therapy, treatment regimen, and monitoring parameters for HIV/HCV-coinfected patients are similar to those recommended for HCV-monoinfected patients.
- E. Metabolic and Other Noncommunicable Comorbidities Associated with HIV, ART, and Aging
 - The availability of highly effective HIV treatment has resulted in longer life expectancy for PLWH and a larger proportion of PLWH who are aged 50 years or older.
 - 2) For all PLWH aged 50 years or older, providers should closely monitor for and promptly evaluate signs or symptoms of the following conditions that are associated with advanced age, long-term HIV infection, ART, or a combination of these:
 - a. Cardiovascular disease and associated risk factors (e.g., hyperlipidemia, glucose intolerance or diabetes mellitus, hypertension, smoking)
 - b. Osteoporosis and bone mineral density loss
 - c. Hypogonadism
 - d. Neurocognitive decline
 - e. Mental health conditions, such as depression
 - f. Polypharmacy
 - g. Kidney disease
 - h. Certain non-acquired immune deficiency syndrome (AIDS)-related cancers
 - 3) Specific recommendations regarding metabolic and noncommunicable comorbidities include:
 - a. Check lipid levels prior to and within 1-3 months after starting ART. Patients with abnormal lipid levels should be managed according to national guidelines.
 - b. Random or fasting blood glucose and hemoglobin A1c (HbA1c) should be obtained prior to starting ART. If random glucose is abnormal, fasting glucose should be obtained. After ART initiation, only plasma glucose criteria should be used to diagnose diabetes. Patients with diabetes mellitus should have an HbA1c level monitored every 6 months with an HbA1c goal of <7%.</p>
 - c. Baseline bone densitometry (DXA) screening for osteoporosis in post-menopausal women and men aged ≥50 years. Screening for transgender persons should follow national recommendations based on sex assigned at birth and individualized risk of osteoporosis.
 - d. Testosterone replacement therapy for cisgender men should be prescribed with caution and only in those with symptomatic hypogonadism diagnosed based on the presence of symptoms plus low serum testosterone documented on two separate morning lab tests.
 Primary Care Guidance for Persons with Human Immunodeficiency Virus: 2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America: https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1391/5956736

F. Additional Guidelines for Care of Persons Assigned Female at Birth

1) Guidelines for Cervical Neoplasia (modified Algorithm 6 of AHCPR 94-0573):

https://hab.hrsa.gov/sites/default/files/hab/About/clinical-gualitymanagement/adolescentadultmeasures.pdf

- a. Age <21 years: Pap test within one year of sexual activity and no later than age 21
- b. Age 21-29 years: Pap test at time of HIV diagnosis. Repeat yearly for three years. If all tests are normal, repeat Pap test every three years thereafter.
- c. Age <30 years: No HPV testing should be performed unless abnormalities are found on Pap test.
- d. Age \geq 30 years: Pap only (same as for 21-29 years) or Pap with HPV testing. If both tests are negative, repeat Pap with HPV test every three years thereafter.
- e. If three consecutive Pap tests are normal, then a follow-up test should be done every three vears.
- f. Patients with abnormal Pap smears or a history of an untreated abnormal Pap smear should be referred for colposcopy and should receive same management and follow-up as the general population.

Refer to American College of Obstetrics and Gynecology (ACOG) guidelines for management of abnormal cervical cancer screening results: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/10/updatedguidelines-for-management-of-cervical-cancer-screening-abnormalities

- f. Cervical cancer screening should continue throughout the patient's lifetime and not, as in the general population, end at 65 years of age.
- 2) Annual mammograms initiated at age 50 or earlier depending on history
- 3) Treatment for pregnant persons living with HIV recommend referral to specialist (i.e., UCSD Maternal, Child & Adolescent Program)

G. Anal Cancer Screening:

- 1) Persons with a history of receptive anal intercourse or abnormal cervical Pap tests and all persons with genital warts should have an anal Pap test if access to appropriate referral for follow-up, including high-resolution anoscopy, is available.
- 2) Digital anorectal exam should be performed at least annually for asymptomatic persons.
- H. PrEP and Partner Prevention Services Assess HIV status of partner(s) and evaluate for PrEP referral for all patients living with HIV who have not achieved sustained viral suppression. Please note that Ryan White does not provide reimbursement for PrEP services for HIVnegative partners.
 - 1) For guidelines regarding evaluation for and provision of PrEP, please refer to the U.S. PHS Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update. Please note that parts of these guidelines may be outdated, as a second agent (coformulation of emtricitabine and tenofovir alafenamide) received FDA approval for use as PrEP for persons assigned male at birth and may be preferred for certain patients at higher risk of renal and/or bone toxicity.

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

2) For guidelines regarding partner services for PLWH, please refer to the Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm

- I. HIV Management Guidelines for Transgender Individuals Primary care of transgender PLWH should address the specific needs of this population and include careful attention to potential interactions between gender-affirming therapy and ART and/or OI prophylaxis medications. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, from the Center of Excellence for Transgender Health at the University of California, San Francisco, include recommendations for transgender individuals living with HIV and can be accessed at https://transcare.ucsf.edu/guidelines.
- J. Interim Guidance for COVID-19 and PLWH At the time of revision, the County of San Diego was in a state of emergency due to the rapidly evolving Coronavirus Disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

While the limited data currently do not indicate that the course of COVID-19 in PLWH differs from that in persons without HIV, caution is warranted. Some people with HIV may have comorbidities (e.g., cardiovascular disease, lung disease, chronic smoking) that increase risk of more severe disease.

- 1) All patients should maintain on-hand at least a 30-day (and ideally a 90-day) supply of ART.
- 2) Influenza and pneumococcal vaccinations should be kept up to date.
- COVID-19 vaccination should be administered based on CDC and Advisory Committee on Immunization Practices (ACIP) guidance. http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.
- All patients should receive COVID-19 vaccination when eligible based on California state guidelines.
- 5) Telephone and virtual visits for routine non-urgent care should be considered as an option to encourage retention in care.
- 6) For further guidance, please refer to the U.S. PHS Interim Guidance for COVID-19 and Persons with HIV, available at <u>https://clinicalinfo.hiv.gov/en/guidelines/covid-19-and-persons-hiv.</u>

Source Documents

- Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (DHHS), accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines</u>
- Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV (DHHS), accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/whatsnew-guidelines</u>
- San Diego Tuberculosis (TB) Risk Assessment, accessed on April 19, 2021 <u>http://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/phs/tuberculosis_control_program/SanDiegoRiskAssessment-Adults.pdf</u>
- 4. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV Laboratory Testing – Laboratory Testing for Initial Assessment and Monitoring of Patients with HIV on Antiretroviral Therapy (DHHS), accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/tests-initial-assessmentand-follow?view=full</u>
- Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, 2020 (CDC), accessed on April 19, 2021 <u>https://www.cdc.gov/mmwr/volumes/68/rr/rr6805a1.htm#:~text=CDC%20organized%2020t</u> <u>he%20recommendations%20for,STD%20or%20STD-related%20conditions</u>.
- Interim Guidance for STD Care and Treatment During Disruption of Clinical Services (CDC), accessed on April 19, 2021 <u>https://www.cdc.gov/std/dstdp/DCL-STDTreatment-COVID19-04062020.pdf</u>
- Sexually Transmitted Diseases Treatment Guidelines, 2015 (CDC), accessed on April 19, 2021 <u>https://www.cdc.gov/std/tg2015/tg-2015-print.pdf</u>
- Update to CDC's Treatment Guidelines for Gonococcal Infection, 2020, accessed on April 19, 2021 <u>https://www.cdc.gov/mmwr/volumes/69/wr/mm6950a6.htm?s_cid=mm6950a6_w</u>
- 9. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* 2014 (CDC), accessed on April 19, 2021

https://www.cdc.gov/std/laboratory/2014labrec/2014-lab-rec.pdf

- Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV (DHHS) – Hepatitis B Virus Infection, accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitis-b-virus-infection?view=full</u>
- 11. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV (DHHS) – Hepatitis C Virus Infection, accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitis-c-virus-infection?view=full</u>
- 12. County of San Diego HHSA Ryan White Primary Care Program Information for Patients <u>https://www.sandiegocounty.gov/content/sdc/hhsa/programs/phs/hiv_std_hepatitis_branch/</u> <u>HIVAIDSCareandServices/hiv-aids-care-and-services-resources.html#eligibility</u>
- Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (DHHS) – Laboratory Testing – Plasma HIV-1 RNA (Viral Load) and CD4 Count Monitoring, accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/plasma-hiv-1-rna-viralload-and-cd4-count-monitoring?view=full</u>
- 14. Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2021 (CDC), accessed on April 26, 2021 https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
- 15. 2021 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2021 (CDC), accessed on April 26, 2021 <u>https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html</u>
- 16. Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices, 2019 (CDC), accessed on June 4, 2021 <u>https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a3.htm</u>
- 17. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV (DHHS) – Community-Acquired Pneumonia, accessed on April 19, 2021 <u>https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunisticinfection/community-acquired-pneumonia-cap?view=full</u>
- Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons

 Advisory Committee on Immunization Practices, 2016, accessed on April 19, 2021
 https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm
- Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020, accessed on June 4, 2021 <u>https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm</u>
- 20. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (DHHS) HHS Adults and Adolescents Antiretroviral Guidelines Panel Recommendation for the Long-Acting Injectable Antiretroviral Regimen of Cabotegravir and Rilpivirine, accessed on April 19, 2021 https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hhs-adults-and-adolescents-antiretroviral-guidelines-panel
- HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C American Association for the Study of Liver Disease (AASLD) and Infectious Diseases Society of American (IDSA), accessed on April 19, 2021 https://www.hcvguidelines.org

22. Primary Care Guidance for Persons With Human Immunodeficiency Virus: 2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America, accessed on April 19, 2021

https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1391/5956736

- 23. HIV/AIDS Bureau Performance Measures for Cervical Cancer Screening March 2016 https://hab.hrsa.gov/sites/default/files/hab/About/clinical-qualitymanagement/adolescentadultmeasures.pdf
- 24. Updated Guidelines for Management of Cervical Cancer Screening Abnormalities, American College of Obstetrics and Gynecology (ACOG), accessed on April 19, 2021 <u>https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/10/updated-guidelines-for-management-of-cervical-cancer-screening-abnormalities</u>
- U.S. Public Health Services Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update, A Clinical Practice Guideline, accessed on April 19, 2021 <u>https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf</u>
- 26. Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection (CDC), accessed July 24, 2017 <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm</u>
- 27. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (UCSF Transgender Care), accessed on April 19, 2021 https://transcare.ucsf.edu/guidelines
- 28. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (CDC), accessed on April 19, 2021 <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html?CDC_AA_refVal=http%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html</u>
- 29. Interim Guidance for COVID-19 and Persons with HIV (DHHS) <u>https://clinicalinfo.hiv.gov/en/guidelines/covid-19-and-persons-hiv-interim-guidance/interim-guidance-covid-19-and-persons-hiv</u>

APPENDIX A SAMPLE Sexual Health Risk Assessment Form

Sexually transmitted diseases (STDs) raise the amount of HIV in the body and can make HIV easier to pass to another person. Alcohol and drugs can harm your immune system, stop HIV medication from working properly and increase side effects. To help your doctor help you stay healthy and lower your risk of passing HIV and STDs to others, please answer the following questions honestly. Your answers are entirely confidential.

1.	Have you had sex (oral, vaginal, anal) within the <u>last 3 months</u> ? (If you answered No please skip to #6)		Yes / 🗆 No / 🗆 Decl	ine
2.	In the last 3 months , how many sexual partners did you have? # N	/lale / # _	Female / #	Transgender
3.	How often did you use condoms? □ Always (100%) / □ Most of the Time (75% or more) / □ Sometimes (50	0%) / □ S	Seldom (25%) / □ Ne	ever (0%)
4.	In the <u>last 3 months</u> how many times have you had sex without using a c #Oral / #Vaginal / #Anal; check one: □ Insertive (to		cceptive (bottom) /	Both
5.	In the last 3 months what was the HIV status of your sex partner(s)? (Cl □ Positive / □ Negative / □ Unsure	neck all t	hat apply)	
6.	Have you had any of the following symptoms in the last 3 months? Yes	<u>s No</u>	<u>.</u>	
	Discharge from penis/vagina			
	Burning feeling with urination			
	Sores on your genitals			
	Anal discharge or pain Mucous or blood in your stool			
	Mucous or blood in your stool			
	Throat sores or pain			
	Skin rash	🗆 🗆		
7.	Have you been diagnosed with a sexually transmitted disease (STD, such Genital Warts, and Genital Herpes) in the <u>last 3 months</u> ? (Check one): If you answered yes, did you complete treatment? (Check one):			't know
8.	In the last 3 months have you used non-injection street drugs 9i.e. marij	uana. me	eth. crystal. speed. g	lass, crack.
	ecstasy. cocaine)?		Yes $/ \square$ No	,,
9.	Have you <u>ever injected</u> steroids, hormones, vitamins or street drugs? \Box Y a. If you answered yes, when was the last time you injected?		o	
	b. Did you ever share needles?		Yes / 🗆 No	
10	In the last 3 months do you feel that your alcohol or drug use caused you	i to enga	oe in risky activities	(i.e.
10.	unprotected sex, needle sharing), even once?		Yes $/ \square$ No	(
11.	Would you be interested in help to inform your sex and/ or needle sharing	g partner	(s) of possible HIV e	exposure?
			$Yes / \Box No / \Box May$	be
	swered Yes or Maybe and would like to speak to a Counselor, please tell u Can we leave a confidential message			1:
Text:	Email:			
	Provider/Staff Signature:			

Change History:

Originally adopted by the HIV Health Services Planning Council in July 2000 Proposed changes adopted by the HIV Health Services Planning Council in May 2003 Proposed changes adopted by the HIV Health Services Planning Council in June 2004 Proposed changes adopted by the HIV Health Services Planning Council in September 2007 Incorporated references updated as necessary Proposed changes adopted by the HIV Planning Group on August 9, 2017 Proposed changes adopted by the HIV Planning Group on September 22, 2021

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RYAN WHITE PRIMARY CARE PROGRAM

REPORT ON COMPLIANCE WITH PRACTICE GUIDELINES 2022

STUDY DESIGN AND METHOLDOGY

United Healthcare conducted a medical chart review for the County of San Diego's Ryan White HIV/AIDS Treatment Extension Act of 2009-funded primary medical care clinics between November 22,2022 and January 13, 2023, at the request of the County of San Diego Health and Human Services Agency; Division of Public Health Services; HIV, STD, and Hepatitis Branch. The goal was to determine the quality of care provided to persons living with HIV/AIDS and contractor compliance with established Practice Guidelines, as well as to collect baseline data for future use. The review tool was slightly revised to clarify specific data points and capture additional relevant data. The County of San Diego HIV Health Services Planning Group's Medical Standards and Evaluation Committee reviewed and approved the data elements to be collected during the review.

The entire client registration database was examined, and the eligible population was selected. Eligibility for inclusion in the review required continuous enrollment in the program from October 2021 through September 2022 with a minimum of one medical visit during the 12-month period.

The resulting list was sorted by primary care sites to determine each clinic's patient population. Twentyfive percent of the eligible enrollees, but no fewer than ten patients, were selected as the sample for each clinic. The percent of the clinic's sample population ranged from 25% to 83%. There was a seventy-three percent decrease in the number of patients eligible for inclusion in the review this year.

In order to present an equitable representation of cis-female, trans-female, and trans-male clients, gender selection was biased; charts for 55% of eligible cis-females, 28% of eligible cis-males, 80% of eligible trans-female, and 100% of eligible trans-male clients were reviewed. The resulting sample represents 31% of the eligible Ryan White clients.

The chart below illustrates the percentage of eligible clients reviewed for each site. In this report, clinic sites are lettered A through H; however, to preserve a blinded status, the letters representing each clinic do not coincide with those of the list below.

Clinic Organization	Total Eligible Clients	Number of Charts Reviewed	Percent of total Eligible Clients Reviewed
San Ysidro Health	188	47	25%
SYHC/King Chavez	36	10	28%
SYHC/Chula Vista	19	10	53%
UCSD - Owen	62	16	26%
AIDS Healthcare Foundation	12	10	83%
Vista Community Clinic	27	10	37%
NCHS/TrueCare	12	10	83%
Hillcrest Family Health			
Centers	52	13	25%
Total	408	126	31%

Each medical record was reviewed by a UHC licensed Registered Nurse Case Manager for all services provided from October 1, 2021, through September 30, 2022. The review included medical encounters,

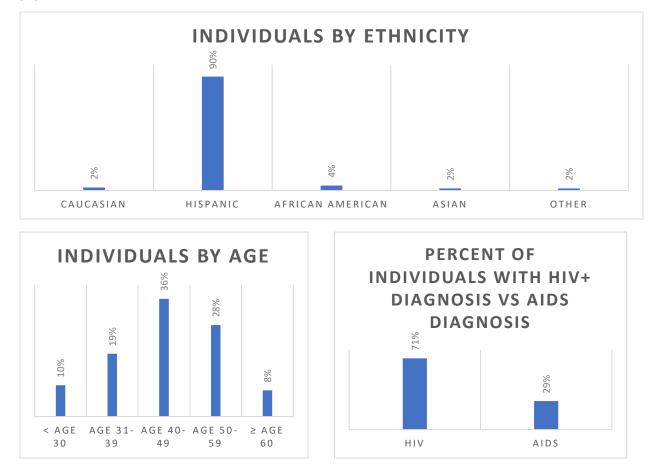
Ryan White Primary Care Program Report on Compliance with Practice Guidelines – 2022 Prepared by United Healthcare Community and State

laboratory test results, medications, documentation of patient adherence, screening tests for sexually transmitted diseases (STD) and tuberculosis (TB), Papanicolaou (PAP) smear tests for cis-females, documentation of dental referrals, hepatitis A, B, and C screening, lipid screening, and vaccinations. Data was entered into Microsoft Excel to ensure accurate and consistent collection.

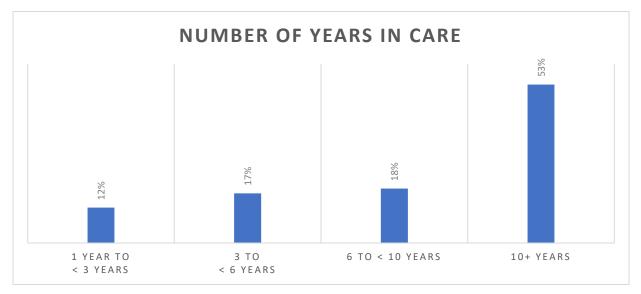
This document reports the overall results of the medical record review. In addition, statistical tests comparing 2021 and 2022 were completed on appropriate measures. Select sections from the review tool are presented anonymously by clinic to provide the County with comparative results of compliance. Subsequent reports detailing individual clinic performance will be provided to the County, which then will review clinic-specific results with each clinic. In addition, certain sections will show benchmarks for comparisons. For further information regarding these benchmarks please visit https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio.

DEMOGRAPHICS

Of the 126 clients included in the sample, 104 (83%) were cis-male, 17 (13%) were cis-female, 4 (3%) MTF, and 1 (1%) FTM. The following charts show additional demographics and data for the sample population:



Because the amount of time receiving care for HIV disease can greatly influence outcomes, the number of years in care (i.e., enrolled in the Ryan White Outpatient Ambulatory Health Services) for the sample population is presented. The chart below shows that 15 (12%) of the sampled clients have been receiving care for one to three years, 21 (17%) three to less than six years, 23 (18%) six to less than 10 years and 67 (53%) for over 10 years or more.



The average number of face-to-face visits per client documented for the 12-month period program-wide was 3, and the average number of telehealth encounters was 1. The total average number of encounters was 3. compared to 4. in 2021.

Summary of Medical Record Review Results – Comparison with the 2021 Review

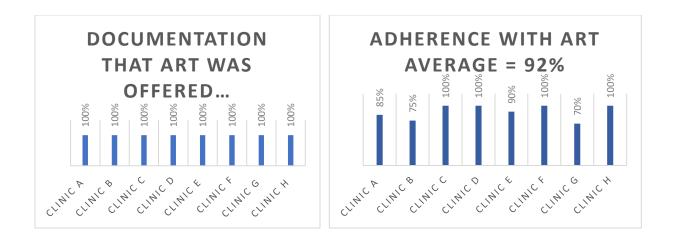
Treatment Plan Adherence

Questions were presented to determine patient adherence to the recommended treatment plan: documentation of follow-up visits scheduled, patient adherence to the schedule, and number of visits missed in excess of 30 days.

The Reviewer found that 98% of the reviewed charts documented the follow-up schedule. This is a decrease of two percentage points from 2021. The current review also revealed that 78% of these patients were adherent to the schedule while 22% were non-adherent (i.e., missing more than one appointment by more than 30 days), a difference of four percentage points compared to 2021.

Antiretroviral Therapy

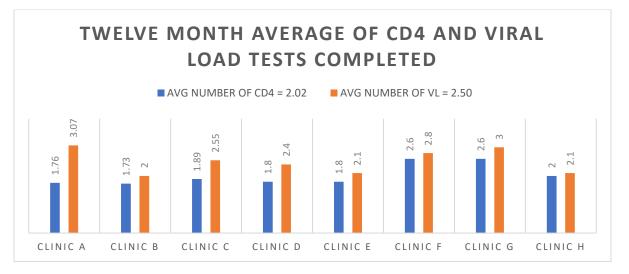
The reviewer looked for documentation that antiretroviral therapy (ART) was prescribed for the clients and found confirmation in 100% of the records reviewed, which is identical to the previous year. Adherence to the medication regimen (i.e., documentation that the individual missed no more than three doses over a 30-day period) was confirmed in 92% of the records compared to 89% in 2021. The results are shown for each clinic in the graphs below.



Frequency and Outcome of CD4 T-Cell Counts and Viral Loads

In December 2015, the San Diego County HIV Services Planning Group's Medical Standards and Evaluation Committee implemented a recommendation to decrease the required CD4 count frequency in certain cases for clients who have sustained undetectable viral load (VL) results For clients who have consistently undetectable VL results on ART and CD4 counts between 300 and 500 for at least two years, the CD4 count only needs to be checked once per year. For clients who have consistently undetectable VL results on ART and CD4 counts over 500 for at least 2 years, CD4 counts are considered optional. These exceptions are listed in the current practice guidelines.

Clients are eligible for up to eight VL test per year. On average, each client received 2.02 CD4 counts and 2.50 VL tests during the twelve-month review. The CD4 count average is higher in this review period compared to the average in 2021 of 1.72. This increase is *not* statistically significant. The average number of viral loads also increased from 1.88 to 2.50. This increase is also *not* statistically significant.



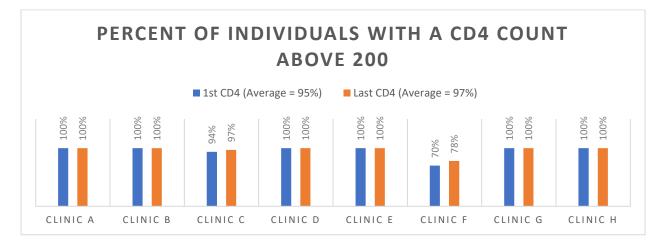
Previous reports used measures that looked at the percentage of clients with HIV infection who had two or more CD4 counts performed during the measurement year. There is currently no comparable measure to use as a benchmark, as the minimum recommended number of CD4 counts varies based on the clinical

Ryan White Primary Care Program Report on Compliance with Practice Guidelines – 2022 Prepared by United Healthcare Community and State situation. The National HIVQUAL measure looks at CD4 counts every four months while the local measure, until recently, has been every three months.

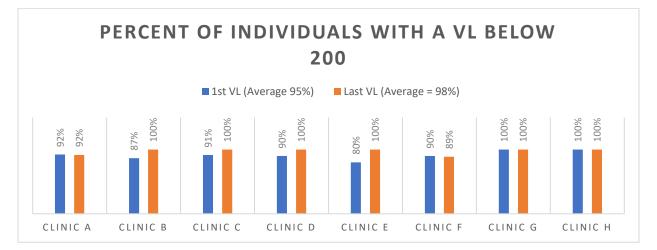
National HIVQUAL: Every 4 months: Percentage of patients for whom at least one VL test was performed in each four-month trimester of the review period at least 60 days apart. Every 6 months: Percentage of patients for whom at least one viral load test was performed in each six-month semester of the review period at least 60 days apart

Outcomes of treatment were evaluated by collecting the values of the first and last CD4 and VL results during the twelve-month period. Parameters were set for CD4 counts greater than 200 cells/mm³ and for VLs less than 200 copies/mL.

Analysis of CD4 counts shows an increase in the percent of clients who received at least two CD4 tests with a count above 200 from first to last (95% to 97%) compared to 2021 (90% to 91%).



VL outcomes showed an increase in the number of clients with results of <200 copies/mL from the first and last testing (95% to 99%)



Ryan White Primary Care Program Report on Compliance with Practice Guidelines – 2022 Prepared by United Healthcare Community and State

Resistance Testing

The Practice Guidelines state that those eligible for genotype testing are patients who are: a) treatmentnaive, or b) patients with a detectable viral load greater than 1,000 copies/mL who have been on stable ART for at least one month at the time of VL testing. In addition, the US Department of Health and Human Services recommends genotypic testing as the preferred resistance testing to guide therapy in ART-naïve patients.

The chart extraction consisted of documenting those records that reported a genotype test during the 12month period. The chart review included a screening for patients with no previous experience with ART.

There were no newly enrolled and treatment-naïve individuals reported in this sample. Last year's review consisted of 4 newly enrolled and treatment-naïve clients who had a documented baseline/treatment-naïve genotype test.

In this year's review, 6% individuals had a VL greater than 1,000. Three out of the seven clients were on a stable ART regimen for at least one month prior to the date of the VL test. Of these three, only one client (33%) had a documented treatment-experienced genotype test. During the 2021 review, 10% individuals were found to have a VL higher than 1,000 and 2 of these clients were on a stable ART regimen for at least one month prior to the VL test. This is a decrease of four percentage points which is *not* statistically significant.

Communicable Disease Screening

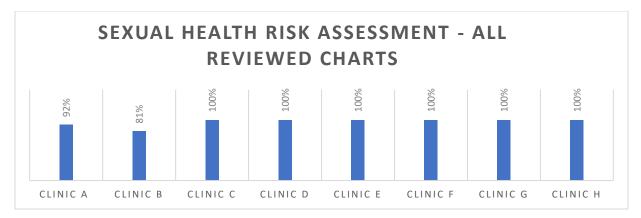
The Practice Guidelines specify the frequency for screening for STDs and TB:

- Sexual risk and drug use assessment should be repeated every three months (once per quarter); screening for syphilis, gonorrhea, and chlamydia shall be done annually at a minimum; and
- Skin testing for TB (PPD or QuantiFERON) shall be completed annually unless already known to be infected/treated.

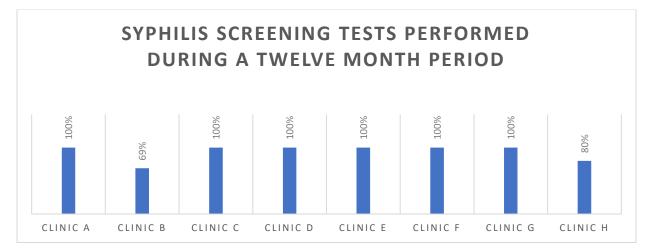
Sexually Transmitted Diseases

Medical records were examined for evidence of either a notation by the practitioner or completion of the Sexual Health Risk Assessment form and laboratory results for STDs (syphilis, gonorrhea, and chlamydia).

Documentation that risk assessment was completed in a twelve-month period was found in 97% of the clients reviewed compared to 67% in 2021. This statistic could be misleading since some patients who have undetectable VLs may be seen only once or twice per year.



Laboratory testing for STDs averaged 94% for syphilis screen across all clinic sites, which is an increase of 66%. This difference is *not* statistically significant.



The charts also were reviewed for evidence of screening for chlamydia and gonorrhea. Screening rates were assessed for each of the following groups (not mutually exclusive):

- Patients who were newly enrolled in care;
- Patients who were sexually active; and
- Patients who had an STD documented in the last twelve months.

All individuals who were diagnosed with an STD in the last twelve months received urogenital screening for chlamydia and gonorrhea. This is a decrease of 18% from last year's results which *not* statistically significant.

There were 2 newly enrolled clients in 2022, both of whom received urogenital screening for chlamydia and gonorrhea. In addition, the percentage of those documented as sexually active who received urogenital screening for chlamydia and gonorrhea increased from 61% to 97%, and this difference *is* statistically significant (p = 0.000. z = 13.4926)

The overall averages using these three criteria are as follows:

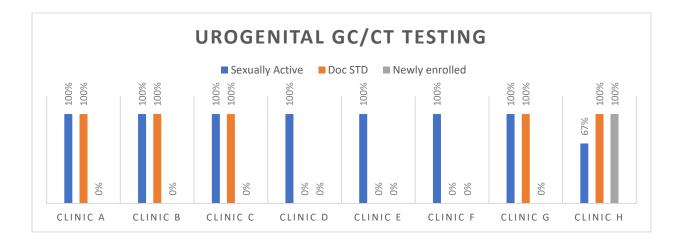
	Newly Enrolled	Sexually Active	Documented STD
Urogenital chlamydia and gonorrhea screening	100%	97%	100%

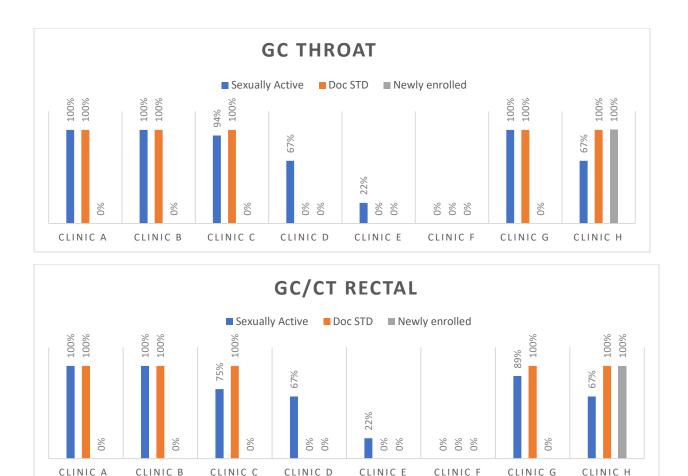
Sixty-seven percent of clients with a documented STD received pharyngeal screening for chlamydia and gonorrhea screening compared to 38% in 2021, a result that is *not* statistically significant. There was an increase of 61% in clients with a documented STD who received rectal screening for gonorrhea and chlamydia from 39% to 100% which *not* statistically significant.

The percentage of clients who are sexually active who received pharyngeal chlamydia and gonorrhea screening increased from 31% in 2021 to 79% in 2022 which is *not* statistically significant. The percentage of sexually active clients who received rectal gonorrhea and chlamydia screening increased from 31% to 67% which is *not* statistically significant. The overall averages for extragenital screening for gonorrhea and chlamydia are presented in the chart below.

	Newly Enrolled	Sexually Active	Documented STD
Pharyngeal chlamydia and gonorrhea screening	100%	79%	67%
Rectal gonorrhea screening	100%	67%	100%
Rectal chlamydia screening	100%	67%	100%

The following graphs represents the results by clinic:

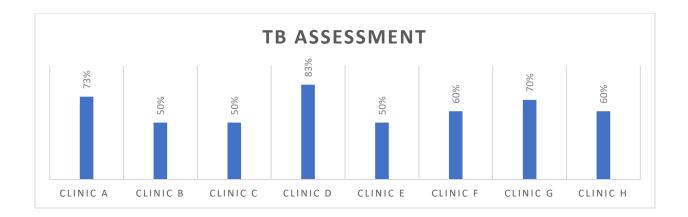




Tuberculosis Testing

To decrease the occurrence of opportunistic infections, persons living with HIV should have an annual TB skin test (PPD), chest X-ray (CXR), or QuantiFERON screening, unless there is documentation of a previous positive reaction. In addition, documentation of a baseline CXR and prophylactic therapy must be present in the medical record for all patients with a previous positive reaction. Medical records were examined for documentation of both items. The percentage of known positives and documentation of prophylactic treatment were collected.

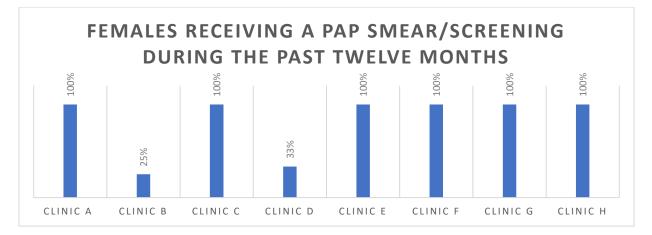
The following chart shows clinic results for the percentage of clients who received testing for TB. Those clients who had a previous positive test were excluded from these figures. Documentation in the medical records indicate that 59% of non-exempt individuals received a TB test during the twelve-month period, an increase of three percentage points. QuantiFERON screening was used 93% of the time, while PPD was used 7% of the time. The study found that 74% of charts for those clients with a prior positive test contained documentation of a CXR or a notation that a CXR had been performed in previous years. This is an increase of 1% from 2021. TB risk assessment for those with prior positive results were found in 63% of the medical records reviewed, which is an increase of 13% over last year's results and *not* statistically significant.



Papanicolaou (Pap) Test

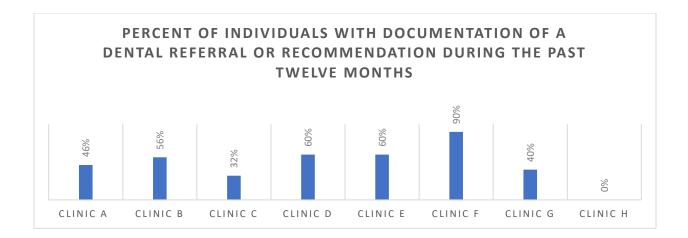
Practice Guidelines for females include an initial and annual Pap smear to screen for cervical cancer unless a hysterectomy for non-dysplasia/non-malignant indications has been performed. A Pap test should be done annually for three years and if normal, can be done every three years thereafter.

The records were reviewed for an indication that the patient's cervical cancer screening had been addressed. Overall, 72% of females had received at least one Pap test during the twelve-month period or had an indication in their chart of when the next Pap smear is due. This represents an increase of 2% from 2021 which is *not* statistically significant. The results by clinic are displayed in the following graph.



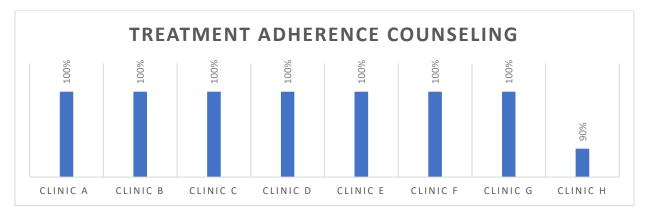
Dental Referral

The contract with the Ryan White service providers requires that the medical records contain documentation that the primary care practitioner referred to or advised the patient about annual dental care. Documentation was found in 44% of the records reviewed, a 1% decrease compared to 45% in 2021.



Treatment Adherence Counseling

The overall average for documenting treatment adherence counseling was 99%, an increase of three percent higher than the previous review. The following graph represents the results by clinic:

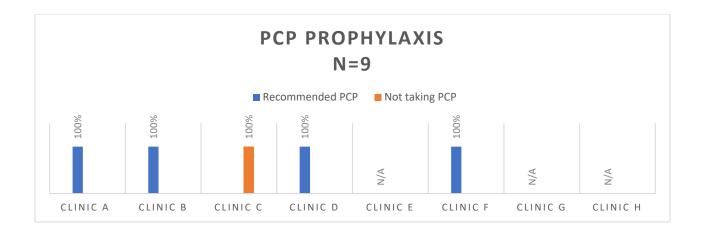


PCP Prophylaxis

The HAB measures for the prescription of PCP prophylaxis is based on the following criteria:

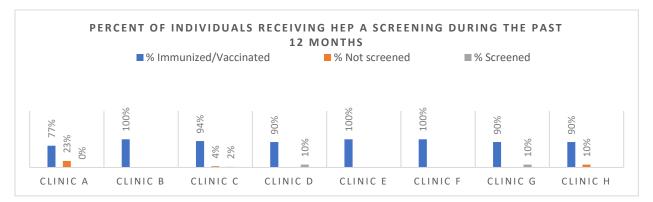
- The client is HIV +
- Is not newly enrolled, and
- Has a CD4 T-cell count <200 unless the post-test after three months rose above 200 cells/mm³

Nine clients met the above criteria and all but 6 were prescribed PCP prophylaxis, constituting a rate of 67%. In the previous year, twenty-one clients met the above criteria and all but 2 were prescribed PCP prophylaxis. This difference is *not* statistically significant.



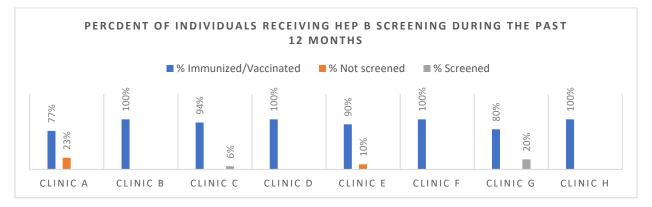
Hepatitis A Screening

Medical records were reviewed for Hepatitis A screening and vaccinations. Overall, 93% of clients were immunized/vaccinated during the review period. This is an increase of 9%, a result that is *not* statistically significant.



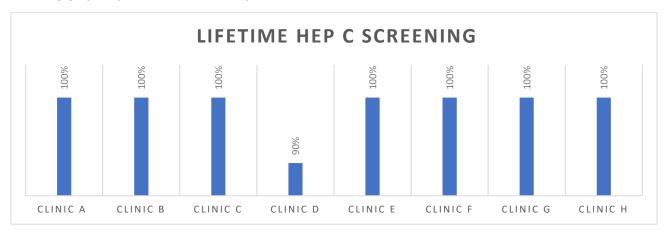
Hepatitis B Screening

Screening for Hepatitis B was also reviewed. Ninety-three percent of clients were immunized/vaccinated compared to 84% in 2021. This measure did consider previous infection and/or the vaccination status of each client. The graph below represents the results by clinic.

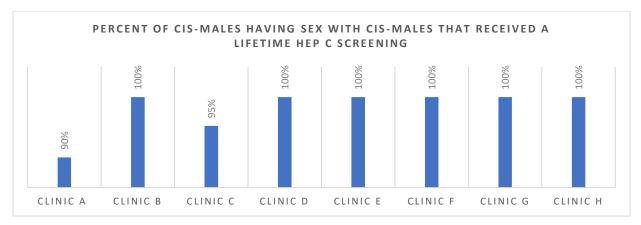


Hepatitis C Screening

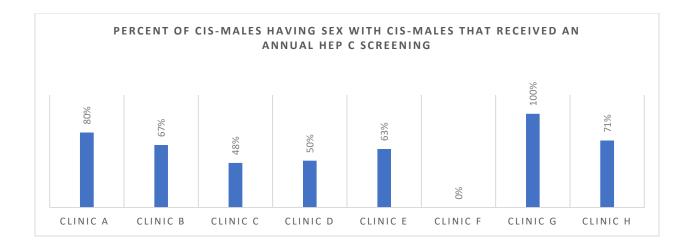
The data also captured those clients who received a lifetime screening for Hepatitis C at any time. In 2022, the numbers of clients who had received a lifetime Hepatitis C Screening at any time or who were previously confirmed with Hepatitis C was 99%, which is an increase of 3% from the previous year. The following graph represents the results by clinic:



Further review of the records revealed that, of the 91 cis-males who reported having sex with other cismales, 97% received a lifetime Hepatitis C Screening. This is a decrease of 5% from the previous year. The following graph represents the results by clinic:

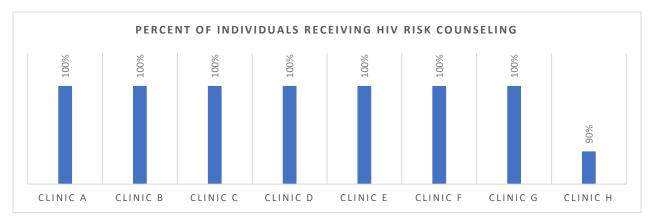


Medical records also were reviewed for documentation that annual Hepatitis C screening was done for cis-males who reported having sex with other cis-males or those with active or previous injection drug use not previously tested for Hepatitis C. It was found that 58% of those eligible for annual Hepatitis C screening based on the criteria above received the screening. This is a decrease of 14% from the previous year which *is* statistically significant (p=0.0287, z=1.9003).

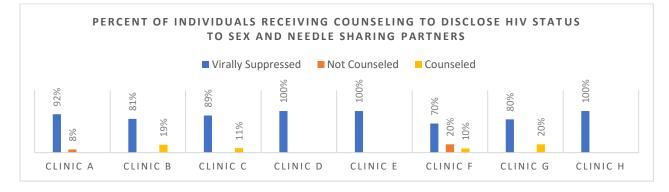


HIV Risk Counseling

Review of the medical records indicated that 99% of the clients received HIV risk counseling, an increase of 16% from the 2021 review period which is *not* statistically significant. The graph below represents the results by clinic:

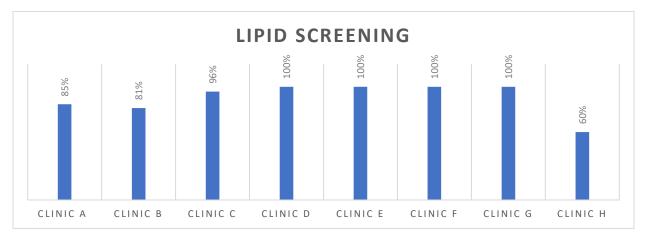


The reviewer also looked for evidence that individuals were counseled on the disclosure of HIV infection to sex and needle-sharing partners and/or were referred to HIV Partner Services if they were not virally suppressed.



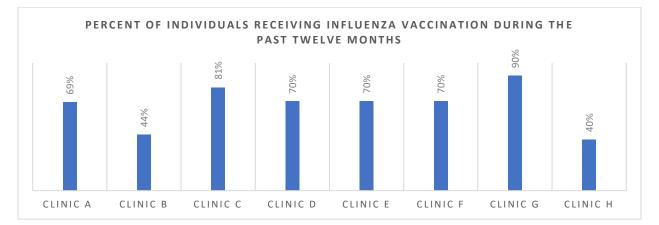
Lipid Screening

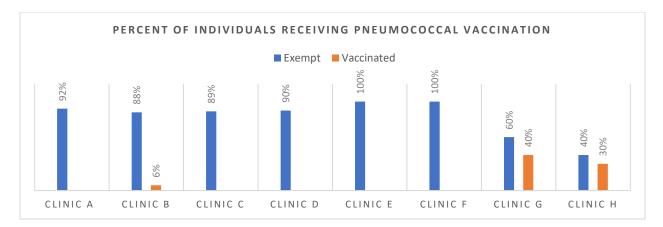
Ninety-one percent of individuals received lipid screening during the 2022 review period. This represents a 12% increase from the previous year. This increase is *not* statistically significant.



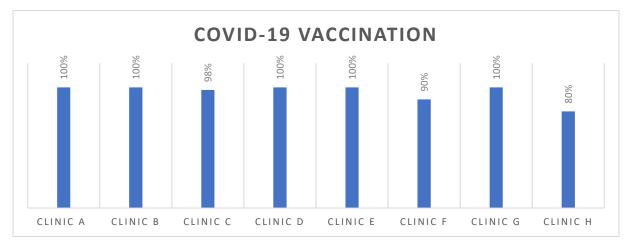
Vaccinations

A review of the medical records showed that 70% of clients received an influenza vaccination, an increase of 32% which is *not* statistically significant. Documentation showed ten percent of patients received a pneumococcal vaccination and 85% were exempt. Of the thirteen clients that were vaccinated during the review period, 38% received Prevnar and 85% received Pneumovax. The following graphs represent the results by clinic:

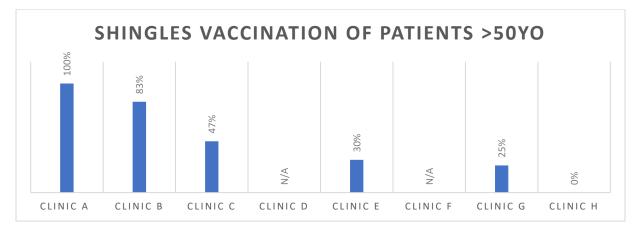


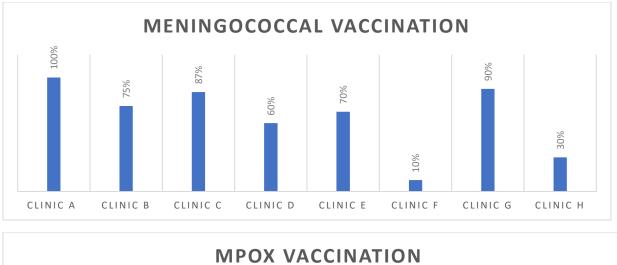


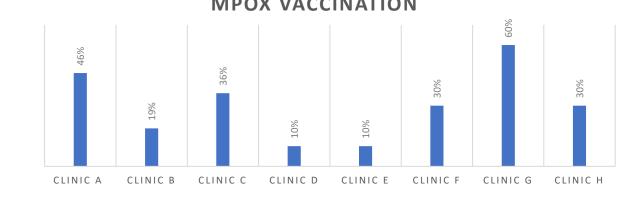
The charts were also reviewed for evidence of COVID-19 vaccination. Of the 126 reviewed, 97% had a documented COVID-19 vaccination. This is an increase of 14% which is *not* statistically significant.



During this year's review, the reviewer also looked for documentation of shingles vaccination for those clients over 50 years of age and, with the emergence of the Monkeypox (Mpox) outbreak, documentation of meningococcal and Mpox vaccination. The records indicated that 44% of those eligible received the shingles vaccine. Seventy-three percent of clients received meningococcal vaccine, and thirty-two percent were vaccinated for Mpox. The following graphs present the results by clinic:







Conclusions

In this review period clients continued to be adherent to their medication regimen and treatment plan. There were also new vaccination measures that were reviewed: Shingles, Meningococcal, and Mpox. The primary overall conclusions and observations from this chart review include:

- Decrease of ninety-two clients from 2021 chart review;
- Decrease in overall visits, including telehealth, to an average of 3 visits compared to 4 in 2021;
- Increases in twelve-month average of CD4 and VL tests (CD4 1.72 to 2.04 and VL 1.88 to 2.50);
- Increase in STD testing for those clients who are sexually active; Pharyngeal chlamydia and gonorrhea screening from 31% to 79%, Rectal gonorrhea/chlamydia from 31% to 67%
- Decrease in number of clients who were diagnosed with a STD from 74 clients to 8, which *is* statistically significant.
- Increase in COVID-19 vaccination from 83% to 97%;
- Shingles for >50 44% received the vaccine;
- Meningococcal 73% received the vaccine; and
- Mpox Of the 32% who received the vaccine, 12% received the second dose within the review period.

Based on the results of the review, there is opportunity to discuss the frequency and level of documentation for certain measures as we move toward the next review period. United Healthcare will be providing individual clinic results as well as feedback from the Nurse Case Manager to use in future discussion with each clinic.



To:CAHAN San Diego ParticipantsDate:April 25, 2023From:Public Health Services

Health Advisory: Potential Access Challenges to Bicillin L-A®

Key Messages

- The Centers for Disease Control and Prevention (CDC) has reported potential access challenges to long-acting penicillin G benzathine (Bicillin L-A[®] or "BIC") for treatment of syphilis.
- Long-acting penicillin G benzathine is the recommended first-line treatment for most forms of adult syphilis, excluding neurosyphilis, and is the <u>only</u> recommended treatment for syphilis during pregnancy.
- Until supplies normalize, providers should prioritize the use of Bicillin L-A[®] to treat pregnant people who are infected with or exposed to syphilis, their sexual partners, and babies with congenital syphilis.
- Bicillin C-R[®] is not interchangeable with Bicillin L-A[®] and should never be used to treat syphilis.
- Contact the local health department if your facility has a shortage or low inventory of Bicillin L-A[®] by calling (619) 692-8501.

Situation

On April 16, 2023, the American Society of Health-System Pharmacists (ASHP) announced a long-acting penicillin G benzathine (Bicillin L-A[®]) shortage. Also, the Centers for Disease Control and Prevention (CDC) has reported that some STD programs are currently unable to procure enough Bicillin L-A[®] to treat syphilis in their jurisdictions.

Background

Pfizer, the sole producer of Bicillin L-A[®], cited increased demand as the reason for the shortage and anticipates that the issue will be resolved in the next two months. Meanwhile, they are working with CDC and the Food and Drug Administration (FDA) to address urgent requests.

Bicillin L-A[®] is the recommended first-line agent for most stages of syphilis, excluding neurosyphilis, ocular syphilis, and otosyphilis. Further, it is the <u>only</u> recommended treatment for *pregnant* people infected with or exposed to syphilis. Doxycycline 100 mg orally BID for two weeks (for primary, secondary, and early latent syphilis) or four weeks (for late latent syphilis and syphilis of unknown duration) is an alternative to Bicillin L-A[®] for treatment of *non-pregnant* people with allergy or other contraindication to penicillin. While Bicillin C-R[®] is a similar pharmaceutical to Bicillin L-A[®], it is <u>not</u> interchangeable with Bicillin L-A[®], as it contains two different types of penicillin, and is <u>not</u> recommended for syphilis treatment.

Thirty cases of congenital syphilis, including one stillbirth, were reported in San Diego County in 2021, with a rate of 76.8 cases per 100,000 live births (a 48.8% increase from 2019 and a 1,013.0% increase from 2013). Ten syphilitic stillbirths were reported in the region from 2013-2021. Congenital syphilis is preventable through timely diagnosis and treatment of syphilis during pregnancy.

Actions Requested

- **1.** *Monitor* inventory of Bicillin L-A[®] at your institution.
- 2. *Prioritize* the use of Bicillin L-A[®] to treat: 1) pregnant people infected with or exposed to syphilis and their partners; 2) babies with congenital syphilis; and 3) persons with allergy or other contraindication to doxycycline (or who are unable to adhere to doxycycline). If supply is adequate to expand use of the medication, other groups to be prioritized include the following (in descending order):
 - Cases of primary and secondary syphilis (including those with positive darkfield microscopy)
 - Cases who meet CDC criteria for early latent syphilis
 - Cases of late latent syphilis or syphilis of unknown duration with high non-treponemal titer (i.e., 1:8 or higher)
 - Cases of late latent syphilis or syphilis of unknown duration with low non-treponemal titer (i.e., 1:4 or lower)
- 3. *Test* for syphilis in persons who present with compatible signs and symptoms and *screen* for syphilis in the absence of signs and symptoms based on CDC recommendations. Screen pregnant persons for syphilis at least twice during pregnancy, including at the first prenatal visit <u>and</u> at 28-32 weeks gestation. Screen at delivery unless the patient had a negative third trimester screen and is not at increased risk of syphilis acquisition.
- **4.** *Notify* the HIV, STD, and Hepatitis Branch (HSHB) of Public Health Services of any shortages or low inventories of Bicillin L-A[®]. You may also contact HSHB for assistance obtaining Bicillin L-A[®] for situations with no alternative treatment options.
- **5.** *Avoid* using Bicillin L-A[®] for conditions other than syphilis (e.g., Group A β-hemolytic streptococcal pharyngitis, primary and secondary rheumatic fever prophylaxis) unless a patient cannot take oral medications. Do not give extra doses of Bicillin L-A[®] in addition to what is recommended by CDC.
- **6.** *Report* all cases of syphilis within 24 hours of diagnosis to HSHB by faxing a Confidential Morbidity Report to (619) 692-8541 or via encrypted e-mail to <u>PHS-HSHB-STDReporting-Fax.HHSA@sdcounty.ca.gov</u>.

Resources

CDC Drug Notices Webpage

ASHP Penicillin G Benzathine Webpage

2021 CDC Sexually Transmitted Infection Treatment Guidelines

Expanded Syphilis Screening Recommendations for the Prevention of Congenital Syphilis (Guidelines for California Medical Providers, 2020)

Thank you for your participation.

CAHAN San Diego

County of San Diego Health & Human Services Agency HIV, STD, and Hepatitis Branch Phone (for providers, M-F 8AM-5PM): (619) 692-8501 (lab/treatment histories and staging/treatment recommendations), (619) 609-3245 (clinical consultations for challenging cases); Fax: (619) 692-8541 E-mail: <u>cahan@sdcounty.ca.gov</u> Secure Website: <u>http://cahan.ca.gov</u> Public Website: <u>http://www.cahansandiego.com</u>



State of California—Health and Human Services Agency California Department of Public Health



GAVIN NEWSOM Governor

April 28, 2023

Doxycycline Post-Exposure Prophylaxis (doxy-PEP) for the Prevention of Bacterial Sexually Transmitted Infections (STIs)

Dear Colleague,

The California Department of Public Health (CDPH) would like to inform all health care providers of a compelling new biomedical intervention to prevent bacterial STIs. Emerging evidence now suggests **doxycycline**, when taken as **doxy-PEP** after condomless oral, anal, or **vaginal sex**, significantly reduces acquisition of chlamydia (CT), gonorrhea (GC), and syphilis.¹ Given the high rates of these STIs in California², CDPH recommends the following:

- 1. **Recommend doxy-PEP** to men who have sex with men (MSM) or transgender women (TGW) who have had ≥1 bacterial STI in the past 12 months.
- 2. Offer doxy-PEP using shared decision-making to all non-pregnant individuals at increased risk for bacterial STIs and to those requesting doxy-PEP, even if these individuals have not been previously diagnosed with an STI or have not disclosed their risk status.¹
- Provide comprehensive preventative sexual health counseling and education to all sexually-active individuals to include HIV/STI screening, doxy-PEP, HIV pre-exposure prophylaxis (<u>PrEP</u>)/HIV post-exposure prophylaxis (<u>PEP</u>), <u>vaccinations</u> (e.g. Hepatitis A/B, <u>Human Papilloma Virus</u>, <u>Mpox</u>, <u>Meningococcal/MenACWY</u>), <u>expedited partner therapy</u>, and/or <u>contraception</u> where warranted.

Evidence:

A <u>randomized controlled trial</u> (RCT) using a single, oral dose of doxycycline 200mg within 72 hours after condomless oral, anal, or vaginal sex in MSM and TGW, who were either persons living with HIV (PLWH) or taking HIV PrEP, showed significant reductions in CT, GC, and syphilis per quarter of study follow up. In persons on HIV PrEP, taking doxy-PEP reduced syphilis by 87 percent, CT by 88 percent, and GC by 55 percent while in PLWH doxy-PEP reduced syphilis by 77 percent, CT by 74 percent, and GC by 57 percent.¹

¹Doxy-PEP has not been studied in transgender men. In a recent randomized trial of 449 cisgender Kenyan women, doxy-PEP was not shown to be protective against STIs³, though pharmacologic studies suggest that doxycycline levels in vaginal fluid should be sufficient to provide such protection.⁴ Further studies – including assessments of adherence – are needed to better understand the reasons why doxy-PEP may have appeared ineffective among women in the Kenyan study.

CDPH STD Control Branch 850 Marina bay Parkway, Bldg. P, 2nd Flr. • Richmond, CA 94804 (510) 620-3400 • (510) 620-3180 FAX Internet Address: <u>www.std.ca.gov</u>



Safety:

Taking doxycycline is safe and well tolerated, with no reported doxycycline associated Grade 2 or higher adverse events (AEs) and no documented laboratory-related severe AEs in the doxy-PEP RCT. Long-term use of doxycycline has been prescribed safely for other medical indications (e.g. <u>acne treatment</u> or <u>malaria prophylaxis</u>).

<u>Unknowns</u>:

Data continue to be collected and reviewed for possible antimicrobial resistance among bacterial STIs, commensal *Neisseria* (as a potential reservoir for tetracycline resistant plasmids), and *Staphylococcus aureus*. The effects of doxy-PEP on the gut microbiome are also being studied.

Prescribing doxy-PEP:

Doxycycline is not FDA approved for STI PEP and there is no national organizational guidance for its use as STI prevention. However, Centers for Disease Control and Prevention (CDC) has released <u>considerations for doxy-PEP</u> as an STI preventative strategy⁵ and San Francisco Department of Public Health has released their own <u>guidance, including counseling messages</u>.⁶

- i. **Prescribe 200 mg of doxycycline taken within 72 hours** (ideally within 24 hours or as soon as possible) **after condomless oral, anal, or vaginal sex.** Doxycycline can be taken daily depending on sexual activity, but no more than 200 mg every 24 hours.
- ii. Screen for GC and CT at all anatomic sites of exposure (urogenital, pharyngeal, and/or rectal), as well as test for syphilis and HIV (if not known PLWH) at initiation of doxy-PEP and every three months. If diagnosed with an STI, treat according to standard <u>CDPH</u> and <u>CDC</u> STI treatment guidelines.
- iii. Rule out and counsel persons who can become pregnant as doxycycline should not be taken during pregnancy.⁷
- iv. Consider hematopoietic, renal, and hepatic laboratory monitoring as clinically indicated in addition to counseling patients on standard precautions and warnings while taking doxy-PEP, as outlined in the <u>drug package insert</u> (e.g., sun sensitivity, pill esophagitis, and rarely intracranial hypertension).⁸

Please reach out to stdcb@cdph.ca.gov if you have any questions about this guidance.

Sincerely,

Kathleen Jacobson, MD Chief, STD Control Branch California Department of Public Health

CDPH STD Control Branch 850 Marina bay Parkway, Bldg. P, 2nd Flr. • Richmond, CA 94804 (510) 620-3400 • (510) 620-3180 FAX Internet Address: <u>www.std.ca.gov</u>



References:

- 1. Luetkemeyer et al. <u>Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted</u> <u>Infections</u>. N Engl J Med. 2023;388(14):1296-1306. doi:10.1056/NEJMoa2211934
- 2. CDPH 2020 STI Surveillance Report
- Stewart et al. "<u>Doxycycline Postexposure Prophylaxis for Prevention of STIs among</u> <u>Cisgender Women</u>." Oral Abstract 121 at: Conference on Retrovirusis and Opportunistic Infections (CROI); 2023 Feb 19-22; Seattle, Washington
- Haaland et al. "<u>Mucosal Pharmacology of Doxycycline for Bacterial STI Prevention in Men</u> <u>and Women</u>." Oral Abstract 118 at: Conference on Retrovirusis and Opportunistic Infections (CROI); 2023 Feb 19-22; Seattle, Washington
- 5. CDC Considerations for Doxycycline as STI PEP: Primary Prevention Methods (cdc.gov)
- 6. San Francisco Department of Public Health, Health Update: <u>Doxycycline Post-Exposure</u> <u>Prophylaxis Reduces Incidence of STIs</u>
- 7. Doxycycline use by pregnant and lactating people: <u>Doxycycline Use by Pregnant and</u> <u>Lactating Women | FDA</u>
- FDA. Package Insert for Doryx[®] (doxycycline hyclate) and Doryx[®] MPC Delayed-Release Tablets. February 2018. <u>https://www.accessdata.fda.gov/drugsatfda_docs</u> /label/2018/050795s026lbl.pdf.

Additional Resources:

- CDPH STD Control Branch Homepage
 - o <u>California STI Screening Recommendations</u>
 - o <u>California STI Treatment Guidelines</u>
- CDC
- o <u>STI Screening Recommendations</u>
- o 2021 STI Treatment Guidelines
- HIV Screening Guidelines
- <u>PrEP & non-occupational PEP guidelines</u>
- Expedited Partner Therapy: <u>CDC</u> & <u>CDPH</u> recommendations and <u>California SB306</u> <u>regulations</u>
- <u>California Prevention Training Center</u> Educational opportunities and training materials for STDs
- <u>STD Clinical Consultation Network</u> Online consultation for questions about evaluation and management of STDs



County of San Diego Monthly STD Report

Nov

1484

481

42

136

651

75

8

157

71

10

21

40

2

2022

Previous 12-

Month Period*

17829

6153

543

1649

7692

1109

100

1539

1076

185

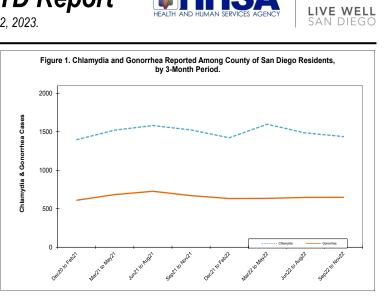
330

561

29

Volume 15, Issue 4: Data through November, 2022; Report released May 2, 2023.





Congenital syphilis * Cumulative case count of the previous 12 months.

Previous 12 Months Combined.

Chlamvdia

Gonorrhea

Primary

Secondary

Early latent

Female age 18-25

Female age 18-25

Male rectal gonorrhea

Early Syphilis (adult total)

Female age ≤ 17

Female age ≤ 17 Male rectal chlamydia

Table 2. Selected STD Cases and Annualized Rates per 100,000 Population for San Diego County by Age and Race/Ethnicity, Year-to-Date

Table 1. STDs Reported Among County of San Diego Residents, by Month and

Nov

1455

499

47

146

602

99

6

109

74

11

31

32

2

2021

Previous 12-

Month Period*

18070

6500

596

1539

8080

1263

136

1390

1283

203

428

652

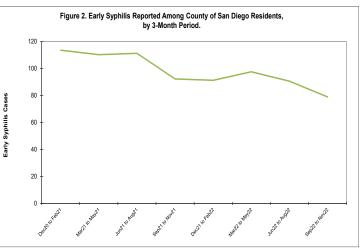
29

-	All Races*		Asian/PI		Black		Hispanic		White	
	cases	rate		rate	cases	rate	cases	rate	cases	rate
All ages										
Chlamydia	16378	538.9	433	129.4	495	341.0	1632	156.5	1726	124.0
Gonorrhea	7066	232.5	185	55.3	430	296.2	1140	109.3	1127	81.0
Early Syphilis	993	32.7	51	15.2	100	68.9	435	41.7	291	20.9
Under 20 yrs										
Chlamydia	2193	270.2	50	66.5	84	212.1	226	65.2	189	62.6
Gonorrhea	531	65.4	9	12.0	52	131.3	86	24.8	47	15.6
Early Syphilis	20	2.5	1	1.3	2	5.0	12	3.5	3	1.0

Note: Rates are calculated using 2021 Population Estimates: County of San Diego, Health and Human Services Agency, Public Health Services Division, Community Health Statistics Unit. 9/2022

* Includes cases designated as "other," "unknown," or missing race/ethnicity.

Note: All data are provisional. Case counts are based on the earliest of date of diagnosis, date of specimen collection, and treatment date. Totals for past months might change because of delays in reporting from labs and providers.



Editorial Note: Potential Access Challenges to Bicillin L-A®

The United States Food and Drug Administration (FDA) has announced a shortage of benzathine penicillin G long-acting (Bicillin L-A®), the recommended first-line agent for most stages of syphilis (excluding neurosyphilis, ocular syphilis, and otosyphilis) and the only recommended treatment for syphilis in pregnancy. Pfizer, the sole producer of Bicillin L-A[®], has attributed the shortage to increased demand due to nationwide increases in syphilis and Group A β-hemolytic streptococcal pharyngitis. According to the FDA, the shortage may persist until the fourth quarter of 2023. As outlined in a recent health alert issued by the County of San Diego Health and Human Services Agency, providers are urged to do the following to mitigate the effects of this shortage on the health of San Diego County residents:

- *Monitor* inventory of Bicillin L-A[®] at your institution. 1.
- **Prioritize** the use of Bicillin L-A[®] to treat: 1) pregnant people infected with or exposed to syphilis and their partners; 2. 2) babies with congenital syphilis; and 3) persons with allergy or other contraindication to doxycycline (or who are unable to adhere to doxycycline). If supply is adequate to expand use of the medication, other groups to be prioritized include the following (in descending order):
 - Cases of primary and secondary syphilis (including those with positive darkfield microscopy)
 - Cases who meet CDC criteria for early latent syphilis
 - Cases of late latent syphilis or syphilis of unknown duration with high non-treponemal titer (i.e., 1:8 or higher)
 - Cases of late latent syphilis or syphilis of unknown duration with low non-treponemal titer (i.e., 1:4 or lower) .





Volume 15, Issue 4: Data through November, 2022; Report released May 2, 2023.

Editorial Note (Continued) :

- 3. Test for syphilis in persons who present with compatible signs and symptoms and screen for syphilis in the absence of signs and symptoms based on <u>CDC recommendations</u>. Screen pregnant persons for syphilis at least twice during pregnancy, including at the first prenatal visit <u>and</u> at 28-32 weeks gestation. Screen at delivery unless the patient had a negative third trimester screen and is not at increased risk of syphilis acquisition [1].
- **4.** *Notify* the HIV, STD, and Hepatitis Branch (HSHB) of Public Health Services of any shortages or low inventories of Bicillin L-A[®]. You may also contact HSHB for assistance obtaining Bicillin L-A[®] for situations with no alternative treatment options.
- **5.** *Avoid* using Bicillin L-A[®] for conditions other than syphilis (e.g., Group A β-hemolytic streptococcal pharyngitis, primary and secondary rheumatic fever prophylaxis) unless a patient cannot take oral medications. Do not give extra doses of Bicillin L-A[®] in addition to what is recommended by CDC.
- 6. *Report* all cases of syphilis within 24 hours of diagnosis to HSHB by faxing a Confidential Morbidity Report to (619) 692-8541 or via encrypted e-mail to <u>PHS-HSHB-STDReporting-Fax.HHSA@sdcounty.ca.gov</u>.





NICK MACCHIONE, FACHE

HEALTH AND HUMAN SERVICES AGENCY

AGENCY DIRECTOR

WILMA J. WOOTEN, M.D., M.P.H. PUBLIC HEALTH OFFICER

PUBLIC HEALTH SERVICES 3851 ROSECRANS STREET, MAIL STOP P-578

APPENDIX (Page 053)

If the physical attendance quorum requirement is met, AB 2449 permits a member who is not physically present to request virtual attendance at the local legislative body's meeting under two circumstances: (1) for "just cause" and (2) due to "emergency circumstances".

Qualifying Reason	Provisions to attend remotely	Requirements/Limitations
"Just Cause"	 There is a childcare or caregiving need (for a child, parent, grandparent, grandchild, sibling, spouse, or domestic partner) that requires the member to participate remotely A contagious illness prevents the member from attending the meeting in There is a need related to a defined physical or mental disability that is not otherwise accommodated for Traveling while on official business of the legislative body or another state or local agency 	A member is limited to <u>two (2)</u> virtual attendances based on "just cause" per calendar year
"Emergency Circumstances"	"A physical or family medical emergency that prevents a member from attending the meeting in person." A member is <u>not</u> required to disclose any medical diagnosis or disability, or any personal medical information that is already exempt from existing law.	A member of the legislative body must make a request to the body to allow the member to meet remotely due to an emergency circumstance, and further must provide a general description of the circumstance justifying such attendance. A request from a member to attend remotely due to an emergency circumstance requires that the legislative body take action and <u>approve</u> the remote attendance at the start of the meeting for the member to be allowed to participate remotely for that meeting ¹ .

¹If the request does not allow sufficient time to be placed on the agenda as a proposed action item, then the legislative body may take action at the beginning of the meeting.

Additional Requirements for a Member Participating Remotely:

In addition to making a request either for "just cause" or due to an "emergency circumstance" for remote appearance, AB 2449 imposes the following three (3) additional requirements on legislative body members seeking to appear remotely at public meetings:

- 1. Before any action is taken during the meeting, the member must publicly disclose whether any other individuals 18 years of age or older are present in the room at the remote location with the member, and the general nature of the member's relationship with any such individuals.
- **2.** A member of the legislative body participating from a remote location must participate through both audio and visual technology.
- **3.** A member's remote participation cannot be for more than three consecutive months or 20 percent of the regular meetings for the local agency within a calendar year. And if the legislative body regularly meets fewer than 10 times per calendar year, a member's participation from a remote location cannot be for more than two meetings.

AB 2449 Checklist

(Applicable January 1, 2023 to December 31, 2025)

Procedures for Public Participation

- Public must be able to remotely hear, visually observe, and address the legislative body either remotely or in person in real time
- □ Public must have the opportunity to participate via: 1) two-way audio or 2) a telephonic service with a webcasting service
- □ Public cannot be required to submit comments prior to the meeting

Procedures for Member to Teleconference from a Remote Location

- □ Member must participate through both audio and visual technology
- Member must disclose adults who are present in the room at the remote location with the member and the general nature of the relationship with those individuals
- Member must submit a general description of the need to teleconference to the legislative body at the earliest opportunity (do not disclose any medical diagnosis or disability)
- □ Member may teleconference for just cause. Just cause is limited to 2 meetings per calendar year (see "Limits per Member" below). Just cause is defined as:
 - Child care or caregiving need of a child, parent, grandparent, grandchild, sibling, spouse or domestic partner
 - Contagious illness that prevents member from attending in person
 - A need related to a physical or mental disability
 - Travel on official business of the legislative body or another state or local agency
- Member may teleconference due to <u>emergency circumstances</u>, which requires approval of the legislative body and which is defined as a physical or family medical emergency that prevents a member from participating in person
- □ <u>Limits per Member</u>: Just cause and emergency circumstances cannot be invoked collectively for more than: 1) two meetings if the legislative body has fewer than 10 meetings per calendar year, or 2) three consecutive months or 20 percent of regular meetings per calendar year if the legislative body has 10 or more meetings per year. Just cause cannot be invoked more than twice per calendar year.

Procedures for the Board/Commission/Committee/Group

- □ Include instructions on the agenda how the public can participate remotely
- A quorum of the members of the legislative body must participate in person at the noticed location that is open to the public
- A majority of the membership must approve a request by a member to teleconference due to <u>emergency circumstances</u>; include the request on the agenda if received in time
- □ All votes must be taken by roll call
- Meeting must be stopped and no action taken if the broadcast of the meeting or ability of the public to comment is disrupted

TELECONFERENCING RULES UNDER THE BROWN ACT

	Default Rule	Declared Emergency (AB 361)	Just Cause (AB 2449)	Emergency Circumstances (AB 2449)	
In person participation of quorum	Required	Not Required	Required	Required	
Member participation via teleconferencing	Audio or Audio-visual	Audio or Audio-visual	Audio-Visual	Audio-Visual	
Required (minimum) opportunities for public participation	In-person	Call-in or internet-based	Call-in or internet-based and in person	Call-in or internet-based and in person	
Disruption of broadcast or public's ability to comment	Meeting can proceed	No further action taken	No further action taken	No further action taken	
Reason must be approved by legislative body	No	Yes (initial findings and renewed findings every 30 days)	No, but general description to be provided to legislative body	Yes and general description to be provided to legislative body	
Votes must be taken by roll call	Yes	Yes	Yes	Yes	
Member's remote location included on agenda	Yes	No	No	No	
Declared emergency and health official's recommendation for social distancing	No	Yes	No	No	
Annual limits	None	None	Twice per calendar year (limits for emergency circumstances also apply for collective number of times AB 2449 can be used per year)	3 consecutive months/ 20% of regular meetings per calendar year; or 2 meetings per calendar year if body meets less than 10 times per year (collectively with just cause)	
Effective Dates	Ongoing	Expires 12/31/2023	Expires 12/31/2025	Expires 12/31/2025	

HIV PLANNING GROUP 12-MONTH COMMITTEE TRACKING May 2022 - Feb 2023

Medical Standards & Evaluation Committee

MSEC	May	Sep	Nov	Feb	#
Total Meetings	1	1	0	1	3
Member					
Tilghman, Dr. Winston ^C	*	*	NM	*	0
Aldous, Dr. Jeannette ^{N CC}	*	1	NM	*	1
Bamford, Dr. Laura	1	*	NM	*	1
Grelotti, Dr. David	*	*	NM	*	0
Hernandez, Yessica				*	0
Lewis, Robert	*	1	NM	1	2
Lochner, Mikie	*	1	NM	*	1
Ransom, Shannon	*	*	NM	*	0
Spector, Dr. Stephen	*	*	NM	1	1
Stangl, Lisa ^N	*	*	NM	*	0
Quezada-Torres, Karla	*	*	NM	*	0
Zweig, Dr. Adam ^N	1	*	NM	1	2

To vote, a member may not miss three (3) consecutive meetings or six (6) meetings within twelve (12) months.

* = Present

1 = Absent for the month

1 = Absence when there are multiple meetings that month.

Member needs to attend at least one (1) meeting for attendance

JC = Just Cause

EC = Emergency Cause

NM = No Meeting

SAN DIEGO HIV PLANNING GROUP



Orientation

All HIV Planning Group Members and anyone interested in learning more about the HIV Planning Group are welcome!

The orientation will cover:

- An overview of the Ryan White Program
- The purpose and procedures of the HIV Planning Group
- The roles and duties of HIV Planning Group members
- An overview of budget reports



Valencia Park/Malcolm X Library 5148 Market St. San Diego, CA 92114 (Multi-purpose Room)



Thursday, May 18, 2023 2:00 PM - 4:00 PM

Register at:

https://forms.gle/iAikLaCD <u>Fne7pqZm6</u>



To request Spanish interpretation services, please let HPG Support know at least **96 hours** in advance.

For additional information or to request translation services, please send E-mail to: **HPG.HHSA@sdcounty.ca.gov**

