# HIV care protocols

**patient linkage, clinic flow, retention, adherence, risk reduction, partner counseling, perinatal management, in-patient coordination, clinic policies and quality management**

[updated 4/18/2016]

## *Linkage: Patient with new diagnosis of HIV

1. **Lab confirmation and referral**: The clinician confirms diagnosis with laboratory documentation of a positive HIV RNA viral load, positive HIV antibody test or 4th generation HIV Ab/Ag test with an HIV 1/2 differentiation or RNA confirmation.
    a. If there are any questions about test results, for immediate assistance the clinician may call the HIV Warmline: 1-800-933-3413.
    b. For immediate assistance with HIV test disclosures and counseling, or the referral process, call the HIV linkage coordinator at your care site.

2. **Baseline labs, to get as soon as diagnosis is confirmed**: Please refer to the list of baseline labs on the next page to order labs as soon as possible. Guidelines, references and explanations for these labs are described in the attached HIV Health Care Maintenance document. The starred labs (*) are of highest priority.

3. **Intake appointment**: Contact the HIV team medical assistant or scheduler to secure a same-day drop-in appointment, or if one is not available, a one-hour intake appointment with an HIV provider in the 1-2 weeks. If the patient is sick with what might be an HIV-related problem but is stable for outpatient follow-up, contact the HIV team to schedule for an urgent drop-in slot for an HIV provider the same week.

4. **Clinical sign-out**: The clinician provides a case sign-out to the HIV provider in-person, via phone or HIPAA-secure encrypted email.

5. **Linkage facilitation:** The clinician calls the HIV linkage coordinator who will:
    a. Arrange for new intake appointment with the HIV provider within the next 1-2 weeks if even a brief appointment is available the same day.
    b. Keep track of the patient to ensure a warm hand-off and successful linkage to care.
    c. **Insurance:** Arrange a time for the patient to receive HIV health education counseling and evaluation for Medi-Cal, HealthPAC or Covered CA coverage.
    d. **ADAP:** The patient should immediately enroll in ADAP (AIDS Drug Assistance Program) especially if the patient is on HealthPAC, Covered CA or other private insurance plan. ADAP will also help pay for co-pays for those with high share-of-costs.
    e. Facilitate the patient to receive partner counseling and community services as needed.

6. **During the initial appointment**
    a. The patient's information is entered into the EHR HIV template (if applicable) by the HIV team medical assistant (MA). See the protocol for "all clinic visits" below.
    b. The MA reviews the standing orders protocol and checks for baseline lab results. (See attached HIV standing orders.)

c. The clinician seeing the patient follows the "HIV Healthcare Maintenance and Screening" guidelines (see attached) for initial history.
d. HIV history is recorded in LabTracker, in the paper chart, or under a NextGen HIV chronic condition (ICD9 code 042), including date of diagnosis, CD4 nadir, linkage, risks, partner history, OI and STD history, genotype and ART history, adherence notes and significant treatment interruptions.
e. Risk reduction and partner counseling is documented according to protocols below.
f. The clinician notifies the HIV team MA on any follow-up issues before the next appointment – prescriptions, adherence checks, insurance coverage, etc.
g. Documentation: where applicable, the provider writes the date of linkage on the i2i tracking sheet and under the NG HIV chronic condition.

## *Baseline labs

When possible, please order these baseline labs ASAP, on the same day as diagnosis disclosure, and even before the first HIV visit, if it's not the same day. Guidelines, references and explanations for these labs are described in the attached HIV Health Care Maintenance document. The *starred labs are of highest priority, in case the patient would like to split up the lab draws. Some Quest lab codes are provided for HIV labs for your reference which phlebotomists may not be familiar with. As of this writing, Quest will only perform HIV labs Monday-Thursday, and Quantiferon tests are often only processed in the afternoons Monday-Thursday.

*HIV viral load, Quest 40085x
*CD4 count and %, Quest 7924X
*HIV genotype, Quest 11189x; if integrase exposure, also order integrase genotype: Quest 16868
*CBC with differentiation
*Complete metabolic panel, including renal and liver function
*Hepatitis B sAg
*Hepatitis C Ab +/- reflex to RNA
*Urinalysis with microscopy; you may consider checking microalbumin
*HLA B*5701 if considering Abacavir, Quest 19774x
Hepatitis A total Ab
Hepatitis B sAb, cAb
Lipid profile
HgA1C
VZV IgG
GC/CT NAAT (urethral, vaginal, rectal, pharyngeal depending on exposure risk)
RPR
Quantiferon TB IGRA
Toxoplasmosis IgG

## *New transfer patient

1. Referring clinics call or email the HIV linkage coordinator, who:
    a. reviews the transfer with the HIV provider and puts the referring clinician in touch with the HIV provider.
    b. requests that the clinic have a release of information to fax or send medical records, including all recent labs, for that patient to the HIV ACCESS clinic.
    c. arrange for new intake appointment with the HIV provider within 8 weeks after the patient's last visit with the previous provider.
    d. remind and ensure that the patient comes to the first clinic appointment.

2. During the initial transfer appointment

a. The patient's information is entered into the i2i system, where applicable, by the HIV team medical assistant (MA). See the protocol for "all clinic visits" below.
b. The MA reviews the standing orders protocol and checks for existing lab results. (See attached HIV standing orders.)
c. The clinician seeing the patient follows the "HIV Healthcare Maintenance and Screening" guidelines (see attached) for initial history if not already covered in prior records and documents HIV history in NextGen under the HIV chronic condition field.
d. The clinician notifies the HIV team MA on any follow-up issues before the next appointment – successful prescription fills, adherence, insurance coverage, etc.

## *All clinic visits: adherence, risk reduction and partner counseling

## Team Huddle

1. Team huddle before the start of clinic: clinician and MA
    a. The clinician reviews the patient list for the day.
    b. The MA prepares i2i or LabTracker visit summary sheets for review.
    c. The clinician discusses active issues for each patient with MA and lets her know if there are action items to work on prior to when the clinician sees the patient (e.g. retrieving records or labs, detailed review of medications, referrals, vaccines)

## MA intake

2. Patient arrives, and MA brings her/him to the Unit
    a. Vital signs and medication reconciliation are recorded in the chart
    b. Vital signs taken and recorded
        i. Weight
        ii. Blood pressure
        iii. Heart rate
        iv. Tobacco screen
        v. Mental health screen if not already documented
        vi. Temperature for patients with cold, cough, fevers, chills or acute illness
        vii. Pulse ox for patients with respiratory complaints (shortness of breath, cough)
    c. Patient agenda-setting
        i. Ask patients about their complaints, questions, and other issues
        ii. Consider using an agenda-setting chart to help them decide
        iii. Help them choose their top three priorities and list them in order
        iv. Let them know that we will try to address the top three and probably will not have time to get to the other items
        v. The MA records the agenda items in the NextGen HPI template under "other"
    **d. MA-directed adherence and medication reconciliation**
        i. Review their medication lists, compare to pill bottles, enter changes in the chart
        ii. Ask about adherence, how well they have taken their medications, how many missed doses (note which ones), and note the timing of the HIV medications, including if they are taken with food or not in the chart.
    e. Quality initiatives
        i. Note any current quality initiatives, and record in the chart for that day. For example, if current quality initiative is dental referrals, then ask patient when the last time they saw the dentist, and if they have an appointment to see them, record in the progress note for that day.
        ii. For any quality measure with an alert: discuss with clinician (for example, yearly pap smear, hep B vaccine, flu vaccine, partner testing, hepatitis C treatment evaluation, colo-rectal cancer screening, etc.)

## Clinician visit

3. The patient is seen by the clinician, who reviews:
    a. Agenda items and complaints
    b. Adherence (and provides counseling)
    c. Preventive health needs, including partner services and harm reduction
    d. Does exam and any other physical intervention
    e. Makes assessment and plan with patient
    f. Writes out prescriptions, lab slips, and referrals
    g. Notifies the MA of any other issues that require follow-up before the next visit
    h. Updates quality measures on the i2i or LabTracker summary printout.

## 4. Adherence Counseling at each visit (MA, RN, case manager, clinician)

a. Assess adherence in a neutral and open way:
    a. How are you doing with your medications?
    b. How many doses do you think you missed in the last month?
    c. How many doses did you take more than an hour off your scheduled time?
    d. What time are you taking your medications? What reminders do you use? Is it working for you?
    e. Viral loads: show how viral load measure correlate with adherence
    f. Pharmacy refill tracking: completed bottle and picked up on time?
    g. Specific medications provide lab clues: AZT and increased MCV, atazanavir and increased unconjugated/indirect bilirubin
b. Listen and try to understand beliefs around medications
c. Assess side effects
d. Review strengths with adherence, ask about needs and expectations
e. Reinforce that the highest level of adherence possible will have best outcomes.
f. Action plan for adherence. Evidence-based strategies (2004 APHA) include:
    a. Tailor the regimen to the patient's needs and schedule
    b. Simplify the regimen and reduce side effects when possible
    c. Address and treat side effects
    d. Pill boxes
    e. Alarms: on phone, on clock
    f. Incorporate pill taking with daily cues: brushing teeth, taking a shower, breakfast, daily newscast, favorite TV shows, bedtime, etc.
    g. Address cultural issues and beliefs: cold/hot, stigma, etc.
    h. Regular, consistent clinic visits to provide med recon and counseling
    i. Enlist the help of the team (MA, program coordinator, providers)
    j. If available: incentives for coming in, viral load suppression
g. Documentation: provider documents counseling done in the progress note or i2i sheet.

## 5. Risk Reduction Counseling at intake/PE visit (RN, case manager, clinician)

a. Assess risks
    a. Sexual: Tell me about any sexual activity you've had in the last year.
        1. sexual behaviors, # partners, condom use, STD history, birth control
        2. What do you know about the HIV status of each partner?
        3. How about condom use?
        4. What has made it more difficult to use condoms?
        5. Do your HIV-negative partners take PrEP?
    b. Substance use: AUDIT-C, Tell me about any drug or alcohol use in the last year.
        1. IDU, unclean needles or works, alcohol, MJ, meth, crack, etc.
        2. How do you think it affects your sexual behaviors?
b. Assess barriers to safer sex and/or IDU: coercive partners, stigma, undisclosed status
c. Review strengths with risk reduction: oral sex, cleaning works, condom use, etc.

d. Assess readiness: pre/contemplation, preparation, action, maintenance, relapse
e. Action plan: harm reduction approach, allow patient to develop own action plan.
    a. What are your thoughts about using condoms? Quitting or cutting down?
    b. Sexual: condoms, less risky sex (oral sex, mutual masturbation), abstinence
    c. IDU: sterile supplies, needle exchange (HEPPAC), cleaning works
    d. Substances: using less or fewer types, abstinence
f. Documentation: provider documents counseling done in the progress note or i2i sheet.

## 6. Mental health screening and referrals, at least annually (MA, clinician)

a. The MA administers the PHQ-2/5/9 or similar screening tool at least once a year
   PHQ-2 questions: Over the past two weeks, how often have you been bothered by any of the following problems?
        1. Little interest or pleasure in doing things.
           0 = Not at all, 1 = Several days, 2 = >half the days, 3 = Nearly every day
        2. Feeling down, depressed, or hopeless.
           0 = Not at all, 1 = Several days, 2 = >half the days, 3 = Nearly every day
b. The clinician reviews the PHQ results, discusses strengths & challenges with patient
    a. Review strengths: exercise, social support, spiritual support, work, etc.
    b. Ask about symptoms of major depressive disorder (SIG E. CAPS)
    c. Ask about symptoms of mania: "Do you ever feel so energetic that you don't feel like you need to sleep? Or that you're unable to stop and relax or sleep?"
    d. Ask about symptoms of psychosis: "Do you ever seem to hear or see things that other people don't hear or see?"
    e. Ask about concurrent substance use: "Tell me about any alcohol or drugs you've used in the last few months."
c. The clinician facilitates the patient to develop own action plan
    a. How much does you anxiety, depression (or other symptoms) bother you?
    b. Do you have ideas for what you'd like to do about them?
    c. How do you feel about seeing a counselor? Psychiatrist?
    d. How do you feel about taking medications for your mood symptoms?
    e. How do you feel about developing an exercise plan? Plan for getting back together with your friends? Your temple? Church?
d. If the patient decides to pursue mental health counseling or psychiatric support, the clinician refers to the specialists who best matches the patient's needs.
    a. Mild to moderate cases who can benefit from short-term support can be referred to in-house therapists, such as Karen Lau, who is trained in substance abuse counseling.
    b. Severe cases and actively suicidal or homicidal cases should be referred for a same-day warm hand-off with the in-house behavioral health specialist on-call with an urgent referral to intensive psychiatric care
e. If the patient wishes to start a psychiatric medication, the clinician decides with the patient when and how to start treatment, and which medication to use.
f. Documentation: provider documents counseling done in the progress note or i2i sheet.

## 7. Substance abuse screening and counseling at intake/PE (cm, clinician)

a. Ask with AUDIT-C: answer (points)
   Q1. How often did you have a drink containing alcohol in the past year?
   Never (0), Monthly or less (1), Two to four times a month (2), Two to three times a week (3), Four or more times a week (4)
   Q2: How many drinks did you have on a typical day when you were drinking in the past year?

None, I do not drink (0), 1 or 2 (0), 3 or 4 (1), 5 or 6 (2), 7 to 9 (3), 10+ (4)

Q3: How often did you have six or more drinks on one occasion in the past year?

Never (0), <Monthly (1), Monthly (2), Weekly (3), Daily or almost daily (4)

b. Assess AUDIT-C results: men positive with score 4+, women positive with score 3+
c. Apply SBIRT brief interventions
d. Referral to substance abuse-trained therapist and/or program as needed.
    a. Highland Hospital has a substance abuse day program: Julia Castillo, 510-437-8588, back-up contact is Naomi: 510-437-5137. The patient will have an intake and then support groups 4 days a week, including an evening program.
    b. For Spanish speaking patients with and without Medicaid, the Latino commission family services program is an option: 510-535-2303.

## 8. Partner counseling and testing at intake/PE visit (case manager, clinician)

a. Ask: Tell me about any sexual activity you've had in the last year. How's your sex life?
    a. #, sex/gender, HIV/STD status, casual, anonymous, substances
b. Assess partner risk: HIV negative? STDs? In care somewhere? Tested?
c. Ask about partner status and testing
    a. What are your thoughts about talking with your partner(s) about your HIV?
        1. If not: Would you like my help in disclosing?
        2. Do you have plans to disclose?
        3. What keeps you from talking with your partner?
    b. Has your partner been tested for HIV? When was the last test? Result?
d. Action plan
    a. Disclosure to partner: how and when, connect to help if needed (clinician or health educator assisted disclosure, anonymous public health disclosure)
    b. Partner testing: how and when, connect to testing site if needed
    c. ART: ensure the patient understands the importance of viral load suppression (HPTN 052: 96% reduction in transmission in serodiscordant couples on ART)
    d. PrEP: refer high-risk partners who might be interested for PrEP
e. Documentation: provider documents counseling done in the progress note or i2i sheet.

## 9. Dental screening and referrals, at least annually (MA, clinicians)

a. The clinician examines the patient's mouth, teeth, gums and throat at least once a year during a physical exam
b. Dental specialist exam: At least annually, the clinician works with the MA to refer the patient to a Ryan White dental provider or other dental provider of the patient's choice for a full oral exam and documents the referral in chart or i2i

## MA checkout

10. The MA helps patient check out: reviews labs, referrals and next visit with patient

11. The MA updates handwritten data from the paper printouts into the electronic database.

12. The MA contacts patient on follow-up issues between visits, such as
    a. How a patient is doing with a new medication
    b. How a patient with adherence difficulty is doing with adherence
    c. How a patient is doing with particular clinical symptoms and scheduling urgent follow-up visits as needed
    d. Assistance with referrals if needed

e. Calling patients who have high no-show rates to remind them about appointments
f. Contacting patients who don't show to reschedule and check in with them

## *Retention in care

1. **Patient misses a visit: follow-up at the time of the missed visit**
    a. MA or other unit staff attempts to contact the patient on the same day via phone and associated contacts (family, partner, friends) at least 3 times if time permits. If patient is reached, the MA checks to see how the patient is doing and reschedules the appointment time accordingly.
        i. If there are urgent issues, the patient is rescheduled within the same day and at least in next week.
        ii. If there are no urgent issues, the patient is rescheduled within the next month.
    b. If we are unable to reach the patient the same day, the HIV case manager or linkage coordinator is alerted and will attempt to reach the patient over the next month via phone, text message, email, and/or unscheduled home visits.
    c. An update about patient contact is given to the provider each week.
    d. If the patient cannot be reached by phone, text message, email or in-person within a month, we will send a certified letter to the patient's address.
    e. If the patient still has not responded and/or her/his status has not been verified (e.g. successfully transferred care to another provider) within 3 months after the missed visit, the HIV Coordinator will contact Georgia Schreiber, Linkage Coordinator at the Alameda County Department of Public Health, to investigate the patient's care status: Georgia.Schreiber@acgov.org, 510-268-7650.
    f. Documentation of patient outreach is completed in the chart.

2. **Patient has not been seen or contacted in the last 3-6 months (out of care): monthly review**
    a. The QM team sends the monthly HIV registry report to the clinicians, MA, case manager or linkage coordinator.
    b. The patient's travel and visit status is reviewed by the clinician. For example, the patient is known to be traveling or abroad, and has a follow-up plan upon return.
    c. The HIV case manager is alerted and will attempt to reach the patient over the next month via phone, text message, email and/or unscheduled home visits.
    d. Attempts to contact the patient will be recorded in the NextGen telephone template.
    e. An update about patient contact is given to the provider each week.
    f. If the patient cannot be reached by phone, text message, email or in-person within a month, we will send a certified letter to the patient's address.
    g. If the patient still has not responded and/or her/his status has not been verified (e.g. successfully transferred care to another provider) within 1 month, the HIV Coordinator will contact Georgia Schreiber, Linkage Coordinator at the Alameda County Department of Public Health, to investigate the patient's care status: Georgia.Schreiber@acgov.org, 510-268-7650.

3. **Making patients "inactive" in LabTracker, NextGen or i2iTracks**
    a. Patient is confirmed to have transferred care to another HIV provider.
        i. Patient verbally confirms and names the new HIV provider and next visit.
        ii. Provider confirms transfer of care, verbally or in written form.
        iii. Nursing home residence with HIV consultation confirmed with patient, nursing home staff, or HIV consultant
        iv. The Public Health Department confirms that the patient has moved out of the region and/or has transferred care to another HIV provider.
    b. Patient is confirmed to be deceased by public health or a death registry report.

## *Patients who miss >2 visits (protocol draft)

1. **Patients who miss >2 visits in a 24-month period are at higher risk for mortality** (2014 Mugarvero, et. al.), so we are tracking which patients meet this definition
    - Missed visit definition = patient does not contact us to cancel, reschedule, or come to the appointment
2. **Patients with >2 missed visits in a 24-month period will be flagged on our tracking sheet**
    - The HIV team case manager will monitor # of missed visits/24 months, and flag
    - The tracking sheet will be updated and shared with the team weekly
    - Patients meeting this definition will be reviewed with the monthly QI reports
3. **Personalized intensive case management and retention plans will be developed for each patient**

### Strategies for clients with difficulty engaging in care

1. Assess client for depression, substance use, housing, transportation, childcare, food insecurity, IPV and/or health beliefs that may interfere with engaging in care
2. Engage other members of the care team; the client may connect with particular team members
3. Personalized case management services: youth-focused support, personality matches, etc.
4. Use motivational and strengths-based counseling techniques
5. Unscheduled home visits: friendly and non-judgmental to welcome them to engage in care
6. Consider using financial/travel/food incentives for certain patients

## *Incentives for the most difficult-to-reach patients (HIV care team)

### Selecting clients for financial incentives

Many clients do *not* need incentives to do well, so it's important to carefully select the clients who need the financial incentives to meet care goals, such as coming to appointments, taking medications, and maintaining suppressed viral loads. In agreement with your care team, consider clients who:

- do not come to appointments despite agreeing on appointment times that work for their schedule, reminders, personalized reminder phone calls or text messages, individual coaching about coming to appointments, and any other standard practices.
- do not get labs done despite agreeing to get labs, helping them access labs convenient to them, being flexible about when they get labs, and any other standard practices.
- do not take HIV antiretrovirals consistently despite having had one-on-one adherence counseling sessions, pill boxes or medi-sets, phone or other reminders, accessible pharmacy refills (e.g. mailed to their homes), personalized adherence guidance and coaching.

### Selecting incentives

Ideally financial incentives are ones that help clients meet the needs of other competing priorities (e.g. need for food, household supplies, childcare supplies, school or work supplies, transportation, etc.) so they have time and bandwidth left to take medications, get labs done and come to appointments on time. In line with this goal, when possible, choose a $50 gift card that best suits your clients' needs, such as:

- Visa gift cards, most versatile and accepted at any location that accepts Visa credit cards
- Grocery store gift cards accepted at the store(s) that the clients access most

- Drug or household store gift cards accepted at the store(s) that the clients access most
- Transportation cards for clients who need help paying for transportation

## When/how to dispense incentives

1. Clients receiving incentives are chosen and agreed upon by the care team.
2. The care team agrees upon which care team member will offer the incentive to the client and when.
3. That care team member will decide on the best way to notify the client. For example, if a client has the strongest relationship with the case manager, the case manager can call him and let him know that we have a special program over the next year allowing us to provide for him a $50 Visa gift card once every 3 months when he comes to a scheduled appointment with his HIV medical provider, has gotten labs including a viral load in the last 3 months, and the HIV viral load is <200 copies/ml.
4. Everyone on the care team will try to be as clear and consistent about the rules as possible:
    a) Client candidates will only be given incentives when they:
        1) come to their medical appointments with their HIV providers
        2) and have gotten an HIV viral load labs done within the last 3 months
        3) and the HIV viral load is <200 copies/ml.
    b) Incentives can be given a maximum of once every 3 months, or 4 times each year, with visits separated by at least 60 days.
    c) Incentives are in specific gift card forms and amounts agreed by the team.
    d) The incentives are intended to help the client optimize their care by supporting them to take medications consistently and on time, come to appointments, and get labs.

## Monitoring and discontinuing incentives

1. One designated care team member is primarily in charge of monitoring and managing incentives.
    a. This person keeps track of all incentives purchased.
    b. This person keeps track of all incentives dispensed, when and to which team member and client.
    c. This person will alert the team when any problems arise with incentives used incorrectly (e.g. too many given out in a certain time period, used for clients not agreed upon by the team, or missing incentives, etc.).
    d. This person will alert the team when a client has used up his/her 4-incentive allocation for the year so s/he may be reassessed for continuation or discontinuation of the incentives program.
2. The care team will be notified at any time about a client who no longer needs incentives or no longer benefits from incentives to do well in care. If the team agrees, the incentives for that client are discontinued.
3. After a year (12-month period) of using incentives for a particular client, the care team discusses whether the team needs to continue using incentives for each client.

## *Perinatal patients

Patients who are women of reproductive age with HIV infection should be counseled on their child-bearing wishes and plans, and appropriate birth control should be offered, taking into account potential HIV drug interactions with hormonal contraceptives.

We follow the DHHS clinical guidelines on the care of perinatal patients with HIV, which is updated here: http://aidsinfo.nih.gov/guidelines

Patients who are pregnant or become pregnant under our care should be co-managed with an obstetrician or a family practitioner with obstetric privileges who is experienced in the prevention of vertical transmission of HIV. Our goal is to support a healthy pregnancy and birth and maintain viral load suppression, especially near the time of delivery, so that the baby remains HIV negative. If a clinic does not have in-house obstetricians or family practitioners experienced with prevention of vertical transmission, we refer our patients to East Bay AIDS Center (a Ryan White Part D site) to co-manage HIV ART with East Bay Perinatal Medical Associates, or our HIV providers co-manage directly with the high-risk obstetricians at Highland Hospital (a Ryan White Part D site) or with East Bay Perinatal Medical Associates:

350 30th Street, Suite 208
Oakland, CA 94609
(510) 444-0790 ph
(510) 869-6225 fx
http://www.ebpma.com

Neonatal care for HIV-exposed infants is managed with UCSF Benioff Children's Hospital Oakland, with referrals and coordination arranged prior to birth: contact Dr. Ann Petru (Chief of Pediatric Infectious Diseases) or HIV nurse case manager Teresa Courville at 510-428-3337, tcourville@mail.cho.org.

## *In-patient/out-patient coordination

For HIV ACCESS patients admitted to an emergency room or in-patient hospital service, we:

- Provide coordination of clinical information, with patient consent
- Discuss patient cases with treating providers to optimize quality and coordination of care
- Schedule a hospital follow-up visit at our clinic within 1-2 weeks of discharge
- Review hospital notes and study results to provide outpatient follow-up
- Hospital records and follow-up notes are scanned into the EHR or placed into paper charts
- For patients hospitalized at Highland Hospital, we contact Tonya Tyree, care and retention nurse case manager, at: 510-437-4923 to coordinate in-patient/out-patient care and transitions.

## *HIV clinic policies and procedures

Each HIV ACCESS care site will maintain the following site-specific policies, procedures and forms:

- Informed and deemed consent policies; confidentiality policies and procedures
- Credentialing and staff privileges policies and procedures, hospital & malpractice coverage
- Clinic hours, policies and procedures
- On-call policies, procedures and schedule
- Patient appointment rosters and schedules
- Laboratory procedure and log books
- Pharmacy and medication prescription documentation
- Infection control policies and procedures
- Emergency policies and procedures
- Patient grievance policy and procedures
- Clinical research protocols

## *Monthly quality management (QM) report and team meetings

At least once per month, the HIV team (clinicians, MAs, QM lead and HIV Program Manager) review panel registry reports for patients who are:

- Out of care for 6 months
- Not virally suppressed

…and develops a plan of action for each patient on the registry report.

Once a quarter to every 6 months, the HIV team (clinicians, MAs, QM lead and HIV Program Manager) get together to:

1. Review QM data, with a focus on retention in care, ART coverage, viral load suppression
2. Specific patients who are not retained, are not prescribed ART, or are not virally suppressed are reviewed in detail and an intervention action plan is put in place.

Twice a year, each HIV team meets with other teams in the HIV ACCESS network to review the network QM reports, goals, Pay-for-Performance program, network-wide decisions, and important health care reform and clinical updates. Consumer surveys and involvement with site-level QM are encouraged.

HIV Primary Care ACCESS
Alameda County Coordinated Early Services System

# HIV testing and linkage protocol * updated March 2015

**POLICY:** In accordance with the US Preventive Services Task Force and CDC guidelines, our primary care clinics provide opt-out HIV antibody testing for:

- all asymptomatic patients ages 13-65 at least once in their lifetime
- all pregnant women at least once during their pregnancy
- patients at high risk (men or transgender women who have sex with men, IV drug use, people with HIV+ partner(s)) every 6 months, with testing every 3 months for these patients who have additional risks (multiple partners, STDs, active alcohol or other recreational drug use)
- other patients at risk (multiple sexual partners) at least once a year
- patients with STDs with each new or recurrent diagnosis
- patients with certain comorbid conditions, which would alter or require therapy: hepatitis B, hepatitis C, tuberculosis, varicella zoster in adults, and any other opportunistic illness that suggests an immunocompromised state.

In addition, our community-based HIV programs provide free confidential or anonymous rapid HIV antibody testing to any member of the community.

**PROCEDURE: Clinic Testing**

**Opt-out HIV testing**

1. Include the HIV antibody test with other screening tests:
   a. 4th gen: HIV Ab/Ag" Quest #91431 (Best for higher risk patients; window period 14 days)
   b. ICD-9 V73.89, "screening for viral illness" as the billing code (auto-linked in protocols)
2. Notify the patient what you will be testing them for. Example: "We test everyone's cholesterol, sugar, liver and kidney function, hepatitis and HIV status." Or "Looks like you haven't been tested for HIV or hepatitis B/C, so let's add those tests to your next labs."
3. No documentation is necessary unless the patient refuses the test. If the patient refuses, then document "HIV test refused" and the reason (if known) in the chart.
4. Test counseling is optional, but we strongly recommend asking patients about their sexual and drug use history, especially during intake and physical exams.

**Negative results**

- Let patients know: "No news is good news"
- Reassess risks at future visits, especially annual and physical exams.

**Discordant results**

- HIV Ab+ or Ag+, negative HIV1/2 differentiation, negative HIV1 RNA
- HIV infection is unlikely. There is a small chance that this may be an acute (within 14-day) infection or recent HIV2 infection.
- If low risk (see above) and not sexually active, check 4th gen Ab/Ag test in 1-3 months
- If patient is high risk (e.g. has recent sexual or needle exposure), retest for RNA in 5-10 days to check for acute HIV1 and consider testing for HIV2 viral load: test code 34977x to check for acute HIV2 infection. Call your HIV linkage contact for help.

**Positive: +HIV Ab/Ag, +diff or RNA**

- The patient has confirmed HIV infection
- Use ICD-9 code: 042
- **Follow up is critical!**
- Notify patient to come in for result disclosure within 1 week
- Notify your HIV linkage contact for help with disclosure and immediate linkage
- Counsel on risk reduction (condoms, abstinence, treatment, clean IDU works)
- For women of reproductive age, assess for pregnancy and counsel on birth control and prevention of mother to child transmission.
- Please see the new patient protocol.

Date Printed: 1/5/2015

# Patient Visit Summary (HIV Visit Summary)

| | | | | | | | Last Vitals | This Visit |
|---|---|---|---|---|---|---|---|---|
| Patient ID: | [redacted] | MR: | [redacted] | Age: | [redacted] | DOB: [redacted] Sex: [redacted] | Date: | |
| Name: | [redacted] | | | Race: | [redacted] | | Blood Pressure: | |
| Address 1: | [redacted] | | | Language: | [redacted] | | BMI: | |
| Address 2: | | | | Phone: | [redacted] | | Height (inches): | |
| City: | [redacted] | | | PCP: | | | Pulse: | |
| State: | [redacted] | ZIP: | [redacted] | Insurance: | | | Temperature (F): | |
| | | | | | | | Weight (lbs): | |

PROBLEMS:

MEDICATIONS:

**Alerts:**

Due: Immunization: Flu (i2i)

| **Labs** | C | Date |
|---|---|---|
| ALT | | |
| CD4 (cells/µL) | | |
| Chol | | |
| Cr | | |
| Hgb | | |
| HBsAb | | |
| HBsAg | | |
| LDL | | |
| Platelets | | |
| QFT-TB | | |
| RPR | | |
| Toxoplasma | | |
| HIV 1 RNA PCR ULT | | |
| Genotype | | |
| HAV Ab Total | | |
| HCV Ab | | |
| CD4 | | |

| R | **Other** | C | N |
|---|---|---|---|
| ☐ | Smoking Status | | |
| ☐ | HIV Access - CD4 | | |
| ☐ | HIV - Date of AIDS | | |
| ☐ | HIV - Date of HIV | | |
| ☐ | HIV - Date of entry | | |
| ☐ | HIV - Genotype | | |
| ☐ | **Immunizations** | C | N |
| ☐ | **Due: Flu (i2i)** | | |
| ☐ | HEP A 1 of 2 | | |
| ☐ | HEP A 2 of 2 | | |
| ☐ | HEP B 1 of 3 | | |
| ☐ | HEP B 2 of 3 | | |
| ☐ | HEP B (any dose) | | |
| ☐ | Pneumovax (i2i) | | |
| ☐ | Td | | |
| ☐ | Tdap | | |
| ☐ | | | |

| **Procs / Refs** | C | N |
|---|---|---|
| Transition coverage ide | | |
| Treatment interruption | | |
| Adherence Counseling | | |
| Anal Pap | | |
| Hemoccult Dispensed | | |
| Colonoscopy | | |
| Dental Visit | | |
| Mammogram (Female) | | |
| Mental Health Screen | | |
| Partner Couns. & Testir | | |
| Partner test date | | |
| Physical Exam | | |
| Rectal Exam (MSM) | | |
| Risk Reduction | | |
| Substance Abuse Scre | | |
| Nutrition counselling an | | |
| HepC treatment eval | | |

| **Blood Pressure** | |
|---|---|
| Date | Val |
| | |
| | |
| | |
| | |
| | |
| | |

| **Weight (lbs)** | |
|---|---|
| Date | Val |
| | |
| | |
| | |
| | |
| | |
| | |

| **CD4 (cells/µL)** | |
|---|---|
| Date | Val |
| | |
| | |
| | |
| | |
| | |
| | |

| **CD4** | |
|---|---|
| Date | Val |
| | |
| | |
| | |
| | |
| | |
| | |

| **HIV 1 RNA PCR ULT** | |
|---|---|
| Date | Val |
| | |
| | |
| | |
| | |
| | |
| | |

| **Cr** | |
|---|---|
| Date | Val |
| | |
| | |
| | |
| | |
| | |
| | |



C = Current N = New D = Discontinue R = Referred E = Received F = Refused L = Enrolled U = Un-Enrolled SR = See Results

# HIV Health Care Maintenance and Screening v.3

**What to do * Why we do what we do * A review of the most current adult guidelines**

**April 2016 update * Sophy Wong, MD**

This information is based on the following guidelines:
-DHHS, January 2016 (http://aidsinfo.nih.gov)
-IAS-USA, July 2014, Gunthard, et. al.
-IDSA, November 2013, Aberg, et. al.

**Triage problems** on the first visit; deal with life-threatening issues and consider initiating ART first. Once the patient is stabilized, start filling in the history. Remember to use open-ended questions for assessing risks. Topics that should be discussed in the first stable visit are highlighted with a star★ and in red; the other topics can wait for the next 2-3 visits.

## Medical History

- ★ **HIV**: beliefs around HIV, first known positive test, seroconversion, HIV risk factors, prior HIV meds, PEP, CD4, viral loads, genotypes and ART/partner ART history.
- ★ **OIs**: derm symptoms (zoster hx), PCP, toxo, MAC, CMV (GI or retinitis), crypto, histo, cocci, thrush, TB, recurrent bacterial infections, BA
- ★ **TB**: PPD hx, LTBI treatment, CXR hx, prior TB tx
- ★ **Concurrent medical conditions**: diabetes, CAD, htn, lipids, renal insufficiency, neuropathy, hepatitis
- ★ **STD** hx and tx, particularly GC/C, syphilis, HPV, HSV
- ★ **Mental health** hx: look out for bipolar disorder and affective instability, any history of psychiatric treatment
- □ **Reproductive health** hx : for women, pregnancies since becoming HIV+, plans for pregnancy
- □ Use of **complementary medicine**
- □ Most recent **dental and eye exams**
- □ **Vaccination history**

## Medication History

- ★ **ARV history** as PEP, PrEP or treatment of HIV
- □ **Complementary and OTC medicine**: herbs, pills, etc.
- □ Steroids, body-building supplements, other hormones
- ★ **Drug allergies**

## Health-Related Behaviors

- ★ **Partner notification and testing**: have sexual and IVDU partners been notified and tested? Offer help with testing.
- ★ **Sexual behavior**: MSM, bisexual, heterosexual; bottom/top; anal/oral/vaginal; # partners, steady partner
- ★ **Sexual risk reduction**: discordant partner(s)?; barrier protection; use this as a chance to discuss condoms! (AIII)
- ★ **Sexual, gender identity**: gay, bisexual, lesbian, two-spirit, heterosexual; transgender, transgender health history
- ★ **Drug use**: methamphetamines (what form? IVDU, muscled, smoked, snorted, ingested), cocaine/crack, heroin, street narcotics, MJ, GHB, ecstasy, ketamine (Special K), alcohol, tobacco
- □ **Drug rehab** and quit history; current interest in rehab
- ★ **Drug harm reduction**: needle exchange
- □ **Exercise**
- □ **Diet:** consider taking a 3-day diet history

## Family History

- □ **Premature CAD**
- □ **Malignancies**
- ★ **G6PD**, sickle cell
- □ **Psychiatric disorders**

## Social History

- □ Take an "**HIV IQ**:" What does s/he know already about HIV transmission, natural history, prognosis, CD4, viral loads, treatments, OIs, prevention? Has s/he known others with HIV? How well?
- □ **Health beliefs**: How does s/he feel about HIV, the US medical system? Aversions? How does s/he feel about taking medications? Does s/he believe they work?
- □ **Current priorities**: What is most important to you right now? What do you care about most right now?
- □ **Future beliefs:** What are your hopes for your future?
- □ **Partner hx**: health of relationships, disclosure status, partner(s) tested? Need help with disclosure/testing?
- □ **Social supports:** friends, family, community
- □ **Spiritual support:** spiritual practice and/or community
- □ **Intimate partner violence (IPV)**: past and current
- □ **Incarceration** hx
- □ **Homelessness:** current and historical
- □ **Food**: sources, reliability
- □ **Water source**: ensure clean drinking water supply
- □ **Travel**: birthplace, travel (check for histo, cocci, TB exp)
- □ **Pet status**: cats (bartonella, toxo), reptiles (salmonella)
- □ **Gardening and soil exposure**: toxo, crypto, MAC
- □ **Income,** employment and stability of these sources
- □ **Insurance** issues: uninsured, minimally insured (ADAP, Medi-Cal), Medi-Cal / MediCare (prescription drug issues), or private insurance

- ★ **Emergency contacts**

- □ **Legal issues**:
  - Issues related to **jail/prison and probation**?
  - Issues related to **immigration**?
  - **benefits, social security, disability**?
  - **housing**?
  - Ask about a **DPOA and Living Will**; make sure you revisit this if she doesn't have them.
  - Does she need documentation for issues related to **children and dependents**?

## Physical Exam

General physical exam; pay special attention to:

- □ **Skin**: dermatitis, folliculitis, skin fungus, molluscum, KS
- □ **HEENT** : retinal exam with CD4 < 200, look in mouth for OHL, candida, dentition
- □ **Lymph Nodes**: cervical, axillary, inguinal
- □ **Abdomen**: liver and spleen
- □ **Neurologic status**: mental status, cognition, sensation
- □ **Genital & rectal findings**: discharge, ulcers, warts, fissures, abscesses

## Rating Clinical Practice Recommendations

(IDSA, US PHS rating system)
Strength of Recommendation
A: strong
B: moderate
C: optional
D: should usually not be offered
E: should never be offered
Quality of Evidence for Recommendation

# Baseline Labs

| Test | Repeat frequency | DHHS | PHP / Newman | Hammer | IDSA | Evidence | Reasons & Notes |
|---|---|---|---|---|---|---|---|
| **HIV Ab** | None if confirmed | Y | Y | Y | Y | AI | Confirm dx, benefits eligibility |
| **CD4, absolute and %** | -baseline and repeat 4 weeks later (D, H, I)<br>-Q3-6 months (I, P,D) | Y | Y | Y | Y | -AI for baseline<br>-AII for confirmation<br>-CIII for CD4/CD8 | -If CD4=300-500 & VL UD x2yrs: check CD4 qyear (BII, IDSA AII)<br>-If CD4>500 & VL UD x2yrs: CD4 is optional (CIII) |
| **Viral Load** | -baseline, Q4-8wks till UD, then Q3-6 months<br>-also at initiation, tx failure, 4 wks after start/blip/switch | Y | Y | Y | Y | -AII for baseline;<br>-AIa to monitor ARVs | -for monitoring tx response<br>-If VL UD x1yr, can check Q6mo (CIII; IDSA AII for VL UD x2yr) |
| **Genotype** | Baseline for all HIV-infected pts; can start ART while waiting for results; repeat with virologic failure while on ARVs | Y | Y | Y | Y | -AIII for baseline<br>-AII for virologic failure<br>-AII for preg | -in early infection: more likely to pick up transmitted resistant strains<br>-later on, to guide ARV regimen<br>-Add INSTI genotype if concern for INSTI failure |
| **HLA-B*5701** | If considering ABC as part of ARV regimen | Y | - | - | Y | -AI, Mallal, et al. PREDICT-1 trial, 2007 | -if positive, avoid ABC use (AI)<br>-document result in medical chart (AII) |
| **Tropism** | If considering a CCR5 inhibitor for tx or virologic failure on inhibitor (MVC) | Y | | | Y | -AI for CCR5 tx<br>-BIII for failure | -get phenotypic test (AI)-predicts if CCR5 antagonist (MVC) will work |
| **CBC** | Q3-6 months | Y | Y | Y | Y | AI | Monitor toxicity, check cytopenias |
| **Chem 10** | Q6-12 months | Y | Y | Y | Y | AI | Monitor toxicity, renal function |
| **Hep A totalAb** | Verify once after vax | Opt | Y | Y | Y | AI | If neg and at risk, vaccinate (AI) |
| **Hep B sAg, sAb, cAb** | Baseline and verify once after vax, may repeat if sAg neg at baseline and sAb neg | Y | Y | Y | Y | AI | -If neg, vaccinate, check sAb in 2mo<br>-if cAb+ and sAb-, check DNA and consider vax if DNA neg (AIII) |
| **Hep C Ab** | Repeat Qyear if at risk | Y | Y | Y | Y | AI | -Check RNA if Ab pos to check for chronic infection; consider tx (AI) |
| **LFTs** | Q6-12 months | Y | Y | Y | Y | AIII | Monitor toxicity, check liver fxn |
| **Toxo IgG** | None | Y | Y | Y | Y | -BIII<br>-Repeat CIII | -if neg, counsel on avoiding infxn (pork, lamb, kitten litter)<br>-If pos, prophy for CD4<100 |
| **VZV Ab** | Baseline & verify after vax | - | - | - | Y | -AIII for VZViG<br>-BIII for adult vax<br>-AII for peds vax | -give VZViG if Ab neg and exposed to active VZV in 96h (AII)<br>-VZV vax if Ab neg&CD4>200 (BIII) |
| **RPR or VDRL syphilis screen** | Q3-6 mo, based on risk | Y | Y | Y | Y | -AII, BIII for repeat<br>-AII for LP in neuro or ocular sxs | -if pos, treat!<br>-check LP/CSF w/neuro sxs (AI), active tertiary, tx failure (<4-fold↓) |
| **PPD or IGRA (QFT)** | Annual<br>-note: HRSA req PPDs | Y | Y | Y | Y | -AI for initial<br>-BIII for repeats | - Pos= PPD ≥5mm, QFT+<br>-if pos with neg CXR, tx LTBI |
| **Fasting lipids** | -HRSA req Qyr total chol<br>-baseline, then 6wks after starting PIs<br>-Qyr if normal | Y | Y | Y | Y | AII | -assess need to tx<br>-following PI/NNRTI side effects<br>-HRSA requirement |
| **glucose/A1C** | -check fasting glucose with lipids, Qyr | Y | Y | Y | Y | AII, A/B (USPSTF) | -see lipid notes above |
| **UA, creatinine clearance** | -Baseline, consider for all<br>-Definitely before starting TDF or IDV | | Y | | Y | AI | -all pts, esp Af-Ams have increased risk of nephropathy<br>-TDF and IDV are nephrotoxic |
| **GC/CT, trich** | -baseline for all, trich for women; Q3-6mo if pos/risk | | | | Y | AI for initial screen AII/III for repeat | -at least annual retest for patients at risk (AI), Qyr for all pts (AIII) |

D=DHHS guidelines, P=PHP guidelines, N=Newman guidelines, H=Hammer guidelines, I=IDSA guidelines

## Consider the following tests in certain patients:

-**Urine pregnancy** screen in women of child-bearing age.
-**G6PD** screening in patients with family hx, African or Mediterranean descent; G6PD deficiency leads to a higher risk of hemolysis to the use of dapsone, primaquine and less to sulfas. (Newman & IDSA rec, AII, can be an expensive test ~$200)
-**CMV IgG** in low-risk patients (w/o hx of anal intercourse; assume these pts to be pos); if negative, use CMV-neg blood products; if positive and CD4<50, patients need a dilated eye exam (IDSA, Hammer, Newman, score AII)
- **STD screening details:** *trichomonas* and GC/CT NAAT for women, GC/CT rectal sample culture for patients reporting anal receptive sex, GC/CT pharyngeal sample culture for patients reporting oral receptive sex, GC/CT NAAT first-void specimen for men with urinary symptoms; repeat annually for sexually-active patients and Q3-6 months for patients at higher risk (IDSA, AI)
-**Testosterone**, check morning total testosterone level in men with fatigue, weight loss, libido loss, erectile dysfunction, depression, or evidence of bone mineral density loss; repeat once to confirm; treat hypogonadism if <300 (IDSA AII)

**Not recommended:** Baseline CrAg or MAC blood cx not recommended for asymptomatic screening (IDSA AII to not test).

## Baseline Studies

| Test | Frequency, comments | Evidence, who recommends |
|---|---|---|
| Anal Pap and DRE for anal cancer screen, in pts with hx anal receptive sex | -annual anal pap if remains active and baseline normal<br>-use polyester swab and Thin Prep, 1" in, 15 sec swab<br>-refer ASCUS, LSIL, HSIL to anoscopy w/bx | No large-scale clinical trials on effectiveness; MSM have 20-fold inc risk of anal cancer; IDSA score CII |
| Cervical Pap for women | -baseline and repeat 6 months later<br>-if both normal and CD4>200, get an annual pap<br>-if both normal and CD4<200, repeat q6 months<br>-if at all abnormal, get colposcopy (abn colpos in 64% with CD4<200, 34% with CD4>400) | AI for baseline<br>AII for annual |
| GC/C rectal, pharyngeal swabs for those having anal and/or oral sex | -repeat q6months to annually if sexually active<br>-STD swabs in AHS fridge; rectal Quest code 16506x<br>-use blue package swabs at Ward 86 (lab validated) | BII |
| GC/C cervical and trichomonas for women | -do baseline asx; repeat when sxs present<br>-repeat when doing paps (P) | AII for baseline and sxs |
| Eye exam: dilated optho exam | -CMV retinitis screen annually for CD4<50<br>*don't let the eye exam delay initiation of ARVs | PHP; note that it's controversial to screen pts before ARV start to pick up periph dz |
| Dental exam and cleaning | -q6 months; also ask about flossing, gum-stimulation | PHP, Newman |
| Colorectal cancer screening for pts ≥50 yo | -annual FOBT x 3<br>-or sigmoid q5yrs<br>-or colonoscopy q10yrs | USPSTF score A |
| Mammogram for women > 40 or 50 yo | -ages 40-49 Q1-2 years optional (BII)<br>-ages 50-69 Q1-2 years<br>-ages 70+ q2 yrs | USPSTF score B<br>IDSA score A1, BII for ages 40-49 |
| DXA bone densitometry for at-risk, post-menopausal women and men ≥50 yo | -baseline for pts at risk, post-meno women, men 50+<br>-risks: thin female smokers >40 yo, history of 2 weeks or more on steroids (prednisone 5 mg or more)<br>-after 2+ yrs on bisphosphonates (afterward, no data) | USPSTF score B for >65<br>IDSA AII |
| BMI | -annual, counsel on results | USPSTF score B |

**Other routine health care maintenance practices**:
-annual blood pressure check, annual depression screen, Q2-3 year eye exam with tonometry for patients aged ≥50
-in men who have ever smoked, aged 65-75, abdominal ultrasound to screen for abdominal aortic aneurysm
**-CXR:** definitely in positive PPD or QFT; consider in patients with underlying lung disease for a baseline (IDSA, BIII)

## Vaccines

| Vaccine | Repeat frequency | DHHS | PHP / Newman | Hammer | IDSA | Evidence | Reasons |
|---|---|---|---|---|---|---|---|
| Pneumococcal PCV13/ PPV23 | PCV13 x 1, then PPV23 at least 8 wks later; if previous vax w/PPV23, give PCV13 1yr after; repeat PPV23x1 after 5 yrs | Y | Y | Y | Y | AI | Prevent bacteremia |
| Influenza | Annually | Y | Y | Y | Y | AI | Higher incidence in HIV+ |
| Hep A | at 0, 6 months; test Ab | Y | Y | Y | Y | AI if at risk | Prev fulminant hep, esp in HCV |
| Hep B | Dbl dose; 0, 1, 6 mo; test sAb | Y | Y | Y | Y | AI if at risk | 40 µg → increased response |
| Tetanus (Td) | Q10 yr boost; Tdap once | n/m | Y | n/m | Y | - | Higher incidence in IVDU |
| HiB | Once | n/m | Y | n/m | Y | - | In asplenia or recurrent HiB (I) |
| Varicella | at 0, 3 mo; test Ab | - | - | - | Y | AI for kids | In CD4>200 with neg Ab |
| Zoster | Once | | | | Y | - | Consider in >60yo + CD4≥200 |
| HPV | At 0, 2, 6 mo for 11-12 yo | | | | Y | AI | Prior to sexual activity |

**Do not give live vaccines (yellow fever, OPV, BCG, live typhoid) to HIV+ patients except for the measles vaccine.**
**Consider:** IPV Polio (don't use OPV) catch-up; MMR catch-up in CD4%>15; meningococcal for 11-12 yo +2nd dose 8 wks later
**With travel**: Meningococcal in epidemic areas; IPV catch-up; rabies; inactivated typhoid (AAHIVM)

## Prophylactic Medications (rec by all guidelines)

| Pathogen | CD4 | Agent | Evidence |
|---|---|---|---|
| *Pneumocystis jiroveci* | CD5 <200<br>[DC when CD4>200 x 12 wks on ARVs] | TMP-SMX DS 160/800 mg daily; alt: dapsone 100 mg qday (+ pyrimethamine for toxo) or atovaquone 1500 mg qday | **-CID 40, 2005**<br>**-MMWR 51, 2002** |
| *Toxoplasma gondii* | CD4 <100<br>In +toxo IgG<br>[DC when CD4>200 x 12 wks on ARVs] | TMP-SMX DS 160/800 mg daily<br>-alt: dapsone 50 mg qday + pyrimethamine 50 mg qwk+ leucovorin 25 mg qwk | **-CID 40, 2005** |
| *Mycobacterium avium complex (MAC)* | CD4 <50<br>[DC when CD4>100 x 12 wks on ARVs] | Azithromycin 1200mg qwk or clarithromycin 500mg q12'<br>-alt: rifabutin 300 mg qday, but watch for interactions | **-NEJM 342, 2000**<br>**-AIDS 13, 1999** |
| *Mycobacterium tuberculosis (MTB)* | Any CD4<br>-look out for hx of PPD≥ 5mm, QFT+ | If LTBI (neg CXR, no e/o active dz),<br>INH 300 mg qday + Vit B6 50 mg qday x6-9 mo (AI) | **AII** |

*Also: Prophylaxis for bacterial infections in Sub-Saharan Africa, any CD4 count: TMP-SMX DS 160/800 mg daily (Lancet 353, 1999)

## Screening in Transgender Patients (UCSF Positive Health Program Guidelines)

**FTM:**
-assess masculinization 3, 6, 12 mo after initiation, then twice yearly
-labs: CBC, LFTs, glucose or HgA1C, lipids at 3, 6 months after initiation, then yearly
-routine birth female screening (paps, mammos)

**MTF:**
-assess feminization 3, 6, 12 mo after initiation, then twice yearly
-labs: LFTs, K at 3, 6 months after initiation, then yearly. Prolactin levels 6 mo after initiation, then yearly x 3.
-mammos when >40 yo and on hormonal therapy 10+ years
-routine birth male screening (such as testicular exams, though USPSTF score D)

## Follow-up Frequency

**DHHS guidelines:**
-Q3 months if early asymptomatic HIV
-Q1 months if late-stage HIV, symptomatic, or initiating ARVs till stabilized

**at each visit:**

- Monitor adherence (AIII)
- screen of high-risk behaviors (AII): sexual risk, STD exposure, IVDU
- STD symptoms (AI)
- At least yearly (and ideally at each visit), substance abuse and mental health screening, HIV partner counseling (safer sex – condoms, PrEP for HIV-negative partners, needle exchange, etc.) (AI)

## References

**General Guideline Resources:**
HIV Primary Care: DHHS, IDSA, IAS-USA, US PHS
Resistance: DHHS, IDSA, IAS-USA
OI Prophylaxis and Treatment: CDC, NIH, HIVMA, IDSA
Pregnant Women with HIV: DHHS
Metabolic Complications: IAS-USA, ACTG


Aberg J, et. al. Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus: 2013 Update by the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis 2013.

DHHS Guidelines for the use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents. Available at: http://www.aidsinfo.nih.gov/guidelines. Accessed 18 April 2016.

Hammer S. Management of Newly Diagnosed HIV Infection. NEJM 2005; 353:1702-10.

Havlir D, Stansell J, Shea S. Policy Number 3.70: Positive Health Practice HIV Patient Health Care Maintenance and Screening Guidelines. June 2005.

Newman M. Introduction to HIV Medicine. Rev 37, 2007.

Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration; National Institutes of Health, HIV Medicine Association of the Infectious Diseases Society of America. Incorporating HIV prevention into the medical care of persons living with HIV. Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR Recomm Rep 2003;52(RR-12):1–24.

Gunthard, et. al., Antiretroviral treatment of adulst HIV infection: 2014 recommendations of the International Antiviral Society-USA Panel. JAMA 2014.

Prevention and treatment of opportunistic I\infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed 16 January 2015.

New York State Department of Health AIDS Institute. Clinical Guidelines: HIV and Mental Health. Available at: http://www.hivguidelines.org/clinical-guidelines/hiv-and-mental-health/. Accessed 16 January 2015.

# HIV Antiretrovirals 101

**when to start * what to start * issues to consider**

updated January 16, 2015 * Sophy Wong, MD * East Bay AETC

## When to start HIV antiretrovirals

**In a nutshell: HIV treatment is recommended for everyone. Assess and support patient readiness and ability to adhere to a chosen regimen.**

**DHHS guidelines:** [DHHS November 2014, http://aidsinfo.nih.gov]
-Recommended for All! CD4 <350 (AI), CD4 ≤ 500 (AII) and >500 (BIII)
-regardless of CD4 count in the setting of: pregnancy (AI), AIDS (AI), HIV-assoc nephropathy (AII), HBV coinfection (AIII), at risk of transmitting to partners (heterosexual partners AI, all other partners AIII), age >50 (BIII)
-offer to those with acute or early HIV infection (BII)

**IAS guidelines:** [IAS July 2014; JAMA 312, Gunthard, et. al.]
-recommended for asymptomatic patients with CD4≤500 (AIa) and asymptomatic patients with CD4>500 (BIII)
-at any CD4: opportunistic illnesses (AIa), pregnant women (AIa), chronic hep B (AIIa) or hep C coinfxn (CIII), age >60 yo (BIIa), HIV nephropathy (AIIa), acute HIV (BIII)

**WHO guidelines**: CD4 ≤ 500, WHO clinical stage 3 or 4, TB, hep B, HIV- partner [WHO June 2013; http://www.who.int/hiv/pub/arv/en/]

**Controversies: early vs. deferred treatment**

**Arguments for early treatment:**
• better CD4 gain/retention; fewer OIs, cardiovascular, renal and liver comorbidities; lower rates of AIDS; better response to HBV vaccines, reduction of HIV transmission, a public health benefit [SMART, Kitahata, NA-ACCORD and ART-CC, ACTG 5127, Okulicz JAMA 2014]

**Arguments for deferred treatment:**
• side effects and toxicities; resistance and adherence issues over a longer-term; fewer drug options once resistance occurs [When to Start Consortium, Hecht JID 2006]

(When to start, continued)
**In the setting of an OI:**
-morbidity and mortality lower in patients with OIs who started ART within 14 days after OI tx started (not including TB) [ACTG 5164]
-careful timing in cryptococcal meningitis; reduce ICP first [BIII, COAT 2012]

**In active TB**, optimal timing of initiating ART is being studied, but in general 2-8 weeks after starting TB treatment; WHO recommends to start ART in all patients with TB [SAPIT trial]. Watch for IRIS and continue therapy (AIII). IAS/DHHS recommend to start ART on this schedule, with **DOT**:
• CD4 <50: start ARVs within 2 weeks of TB treatment (AI)
• CD4 =50+: start ARVs by 2-4 wks if severe (BI-III) or by 8-12 wks (AI)
• TB meningitis: start ARVs within 2-8 weeks with help from experts (BIII)
• Pregnant women with TB: start ART asap (AIII)

**Other issues to consider:**
• **ART toxicity**: peripheral neuropathy, anemia, renal insufficiency
• **age> 50 yo**: start asap due to poorer survival without treatment
• **discordant couples**: less transmission when viral load undetectable (HPTN 052 Partners trial, June 2010: 96% reduction in hetero couples)
• **Hep B**: check DNA, use TDF+FTC/3TC (BII), add entecavir if on 3TC monotherapy (BI); avoid treatment interruptions to ↓risk of hep B flares (AII)
• **Hep C**: studies suggest slower liver fibrosis progression in pts on ARVs
• **Women on OCPs**: ART may ↓OCP levels, so choose regimen with no interactions, or use additional or alternative contraception (AIII)
• **CV disease**: consider avoiding ABC, LPV, FPV (IAS rec)
• **Multi-drug resistant HIV**: consider regimen with boosted DRV BID (AI)

How to start → see the HIV health care maintenance handout
• history, physical, risk reduction, partner counseling
• baseline labs, including genotype, CD4, viral load, and HLA-B*5701
• assess patient readiness and preferences: keys to adherence
• interpreting genotypes: Stanford database (http://hivdb.stanford.edu/)
• drug interactions: HIV InSite (http://hivinsite.com/)

Rating of Recommendations: A = Strong; B = Moderate; C = Optional; Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

# What HIV antiretrovirals (ART) to start & ART list (as of January 2015)

**Putting together a regimen:** use 3 active drugs based on genotype
• for ART naïve, generally use 2 NRTIs and 1 NNRTI or boosted PI or INSTI
[symbols: ★use in initial regimens ☼ qday dosing ◈ renal dosing ☠ avoid]

**NRTIs (nucleoside reverse transcriptase inhibitors)**
• 3TC, lamivudine: 300mg qday; low resistance barrier; anti-HBV ★☼◈
• FTC, emtricitabine: 200mg qday; same mech as 3TC; anti-HBV ★☼◈
• TDF, tenofovir: 300mg qday; ☠ in renal failure except HD; anti-HBV ★☼◈
• ABC, abacavir: 600mg qday; CV& hypersens. risk, ☠ in B5701, ☠ VL>100k ☼
• ZDV (AZT), zidovudine: 300mg BID; risk of cytopenia, ☠ in sig anemia ◈
• d4T, stavudine: 30mg BID; risk of pancreatitis, lactic acidosis, PN ☠◈
• ddI, didanosine: 250mg qday (<60kg), 400mg qday (≥60kg); sim to d4T ☠☼◈

**NNRTIs (non-nucleoside reverse transcriptase inhibitors)**
• EFV, efavirenz: 600mg qhs; risk of rash, hepatoxic, ψ; ☠ in 1st tri pregnancy ★☼
• NVP, nevirapine: 200mg BID; risk of rash, hepatoxic esp in CD4>250, lead-in
• ETR, etravirine: 200mg BID; use in NNRTI resistance; risk of rash & hsn
• RPV, rilpivirine: 25mg qday w/food; ☠ PPIs inhibit absorption, ☠ VL>100K ☼

**PIs (protease inhibitors)**
• ATV/r, bsted atazanavir: 300mg+100mg qday; ☠ PPIs inhibit absorption ★☼
• DRV/r, bsted darunavir: 800mg+100mg qday in tx-naïve; BID in tx-exp★☼
• LPV/r, bsted lopinavir: 800/200mg qday or 400/100mg BID; metab/GI sxs ☼
• FPV/r, bsted fosamprenavir: 1400+100 qday or 700+100 BID; metab/GI sxs ☼
•SQV/r, bsted saquinavir: 1000mg+100mg BID; metab/GI sxs; high pill burden
• TPV/r, bsted tipranavir: 500mg+200mg BID; use in PI resistance; hepatoxic

**INSTIs (integrase strand transfer inhibitors)** avoid cation antacid use with these
• RAL, raltegravir: 400mg BID; low resistance barrier; mild GI sxs ★
• EVG, elvitegravir: 150 mg must be used with cobicistat 150 mg qday; ☠ CKD ☼
• DTG, dolutegravir: 50 mg qday or BID w/ INSTI mutations or P450 inducers ★☼

**CCR5-antagonist:** MVC, maraviroc: dosed for interactions; check CCR5 tropism
**Fusion Inhibitor:** T20, enfuvirtide: 90mg SQ BID; salvage tx; injxn site rxns

**Fixed-dose combinations** (all except Kaletra are ◈):
TDF/FTC=Truvada
ABC/3TC=Epzicom
ZDV/3TC=Combivir
LPV-r=Kaletra
ABC/3TC/ZDV=Trizivir
EFV/TDF/FTC=Atripla
RPV/TDF/FTC=Complera
EVG/cobi/TDF/FTC=Stribild (Quad)
DTG/ABC/3TC=Triumeq

**DHHS guidelines for ART naïve:**
**preferred** (AI): (avoid TDF in renal failure)
• **EFV/TDF/FTC = Atripla** (avoid if wanting to get pregnant)
• **ATV-r + TDF/FTC** (not if on PPI)
• **qday DRV-r + TDF/FTC**
• **RAL BID + TDF/FTC**
• **EVG/cobi/TDF/FTC=Stribild** ( in CrCL>70, not if on cation antacid)
• **DTG/ABC/3TC=Triumeq** (if HLA B*5701 neg, not if on cation antacid)
• **DTG/TDF/FTC** (not if on cation antacid)

• **alternative** (AI): EFV+ABC/3TC, ATV-r+ABC/3TC (if HLA B*5701 neg)
• combo pills: RPV/TDF/FTC (Complera; avoid in vl>100k)
• IAS alternatives: regimens containing NVP, LPV-rit, DRV-cobi, ATV-cobi

• **do NOT use**: monotherapy with NRTI or boosted PI (AI), dual-NRTI or triple-NRTI, ATV+IDV, ddI+d4T, dual-NNRTI, EFV in 1st tri pregnancy, FTC+3TC, ETR+ unboosted PI or ATV-r or FPV-r or TPV-r, NVP in tx-naïve women CD4>250 or men >400, unboosted DRV or SQV or TPV, d4t+AZT

**WHO guidelines for ART-naïve**: Adults: TDF+3TC/FTC+EFV (alt ABC or AZT instead of TDF); children 3-10: ABC+3TC+EFV; children<3: ABC/AZT + 3TC + LPV-rit; phasing out d4T

**Also consider: Don't stop once you start!** (AI), resistance barrier of regimen (PI>INSTI>NNRTI), hep B (use TDF/3TC), PUD on PPI (avoid ATV, RPV), cation antacid use (avoid INSTIs), hep C tx (avoid Stribild?)
• **Treatment goals**: long-term HIV VL suppression, restore immunologic function, prolong survival, reduce morbidity, prevent HIV transmission
• **When to switch**: patient intolerance, unacceptable side effects, unavoidable drug interactions, resistance: virologic failure of sustained VL>200, get a genotype on ART & switch based on 2+ active drugs (AI)

Rating of Recommendations: A = Strong; B = Moderate; C = Optional; Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion