FY 2020 Houston EMA Ryan White Part A/MAI Service Definition **Comprehensive Outpatient Primary Medical Care including Medical Case Management, Service Linkage, Outreach, Emergency Financial Assistance - Pharmacy Assistance and Local Pharmacy Assistance Program (LPAP) Services**	
HRSA Service Category Title: **RWGA Only**	1. Outpatient/Ambulatory Medical Care 2. Medical Case Management 3. AIDS Pharmaceutical Assistance (local) 4. Case Management (non-Medical) 5. Emergency Financial Assistance – Pharmacy Assistance 6. Outreach
Local Service Category Title:	Adult Comprehensive Primary Medical Care - CBO i. Community-based Targeted to African American ii. Community-based Targeted to Hispanic iii. Community-based Targeted to White/MSM
Amount Available: **RWGA Only**	Total estimated available funding: $0.00 (to be determined) Note: The Houston Ryan White Planning Council (RWPC) determines overall annual Part A and MAI service category allocations & reallocations. RWGA has sole authority over contract award amounts.
Target Population:	**Comprehensive Primary Medical Care – Community Based:** i. Targeted to African American: African American ages 13 or older ii. Targeted to Hispanic: Hispanic ages 13 or older iii. Targeted to White: White (non-Hispanic) ages 13 or older **Outreach:** Services will be available to eligible HIV-infected clients residing in the Houston EMA/HSDA with priority given to clients most in need. Services are restricted to those clients who meet the contractor's RWGA approved Outreach Inclusion Criteria. The Outreach Inclusion Criteria components must include, at minimum 2 consecutive missed primary care provider and/or HIV lab appointments. Outreach Inclusion Criteria may also include VL suppression, substance abuse, and ART treatment failure components.
Client Eligibility: Age, Gender, Race, Ethnicity, Residence, etc.	PLWHA residing in the Houston EMA (prior approval required for non-EMA clients). Contractor must adhere to Targeting requirements and Budget limitations as applicable.
Financial Eligibility:	*See Current Approved Financial Eligibility for Houston EMA/HSDA*

Budget Type: **RWGA Only**	Hybrid Fee for Service
Budget Requirement or Restrictions: **RWGA Only**	**Primary Medical Care:** No less than 75% of clients served in a Targeted subcategory must be members of the targeted population with the following exceptions: 100% of clients served with MAI funds must be members of the targeted population. 10% of funds designated to primary medical care must be reserved for invoicing diagnostic procedures at actual cost. Contractors may not exceed the allocation for each individual service component (Primary Medical Care, Medical Case Management, Local Pharmacy Assistance Program and Service Linkage) without prior approval from RWGA. **Local Pharmacy Assistance Program (LPAP):** Houston RWPC guidelines for Local Pharmacy Assistance Program (LPAP) services: Contractor shall offer HIV medications from an approved formulary for a total not to exceed $18,000 per contract year per client. Contractor shall offer HIV-related medications for a total not to exceed $3,000 per contract year per client. These guidelines are determined by the RWPC. The RWPC determines the subcategories that shall include Ryan White LPAP funding. Medications must be provided in accordance with Houston EMA guidelines, HRSA/HAB rules and regulations and applicable Office of Pharmacy Affairs 340B guidelines. At least 75% of the total amount of the budget for LPAP services must be solely allocated to the actual cost of medications and may not include any storage, administrative, processing or other costs associated with managing the medication inventory or distribution. **Emergency Financial Assistance – Pharmacy Assistance** Direct cash payments to clients are not permitted. It is expected that all other sources of funding in the community for emergency financial assistance will be effectively used and that any allocation of RWHAP funds for these purposes will be as the payer of last resort, and for limited amounts, uses, and periods of time. Continuous provision of an allowable service to a client should not be funded through emergency financial assistance. **Outreach**

	Outreach services are restricted to those patients who have not returned for scheduled appointments with Provider as outlined in the RWGA approved Outreach Inclusion Criteria, and are included on the Outreach list.
Service Unit Definition/s: **RWGA Only**	• Outpatient/Ambulatory Medical Care: One (1) unit of service = One (1) primary care office/clinic visit which includes the following: • Primary care physician/nurse practitioner, physician's assistant or clinical nurse specialist examination of the patient, and • Medication/treatment education • Medication access/linkage • OB/GYN specialty procedures (as clinically indicated) • Nutritional assessment (as clinically indicated) • Laboratory (as clinically indicated, not including specialized tests) • Radiology (as clinically indicated, not including CAT scan or MRI) • Eligibility verification/screening (as necessary) • Follow-up visits wherein the patient is not seen by the MD/NP/PA are considered to be a component of the original primary care visit. • Outpatient Psychiatric Services: 1 unit of service = A single (1) office/clinic visit wherein the patient is seen by a State licensed and board-eligible Psychiatrist or qualified Psychiatric Nurse Practitioner. This visit may or may not occur on the same date as a primary care office visit. • Nutritional Assessment and Plan: 1 unit of service = A single comprehensive nutritional assessment and treatment plan performed by a Licensed, Registered Dietician initiated upon a physician's order. Does not include the provision of Supplements or other products (clients may be referred to the Ryan White funded Medical Nutritional Therapy provider for provision of medically necessary supplements). The nutritional assessment visit may or may not occur on the same date as a medical office visit. • AIDS Pharmaceutical Assistance (local): A unit of service = a transaction involving the filling of a prescription or any other allowable medication need ordered by a qualified medical practitioner. The transaction will involve at least one item being provided for the client, but can be any multiple. The cost of medications provided to the client must be invoiced at actual cost. • Medical Case Management: 1 unit of service = 15 minutes of direct medical case management services to an eligible PLWHA performed by a qualified medical case manager. • Service Linkage (non-Medical Case Management): 1 unit of service = 15 minutes of direct service linkage services to an

	eligible PLWHA performed by a qualified service linkage worker. • Outreach: 15 Minutes = 1 Unit • Emergency Financial Assistance – Pharmacy Assistance: A unit of service = a transaction involving the filling of a prescription or any other allowable HIV treatment medication need ordered by a qualified medical practitioner. The transaction will involve at least one item being provided for the client, but can be any multiple. The cost of medications provided to the client must be invoiced at actual cost.
HRSA Service Category Definition: **RWGA Only**	• **Outpatient/Ambulatory medical care** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). Primary medical care for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service's guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies. • **AIDS Pharmaceutical Assistance (local)** includes local pharmacy assistance programs implemented by Part A or Part B Grantees to provide HIV/AIDS medications to clients. This assistance can be funded with Part A grant funds and/or Part B base award funds. Local pharmacy assistance programs are not funded with ADAP earmark funding. • **Medical Case Management** services (including treatment adherence) are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence

	to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication. • **Case Management (non-Medical)** includes the provision of advice and assistance in obtaining medical, social, community, legal, financial, and other needed services. Non-medical case management does not involve coordination and follow-up of medical treatments, as medical case management does. • **Emergency Financial Assistance** provides limited one-time or short-term payments to assist the RWHAP client with an emergent need for paying for essential utilities, housing, food (including groceries, and food vouchers), transportation, and medication. Emergency financial assistance can occur as a direct payment to an agency or through a voucher program. • **Outreach Services** include the provision of the following three activities: Identification of people who do not know their HIV status and linkage into Outpatient/Ambulatory Health Services, Provision of additional information and education on health care coverage options, Reengagement of people who know their status into Outpatient/Ambulatory Health Services
Standards of Care:	Contractors must adhere to the most current published Part A/B Standards of Care for the Houston EMA/HSDA. **Services must meet or exceed applicable United States Department of Health and Human Services (DHHS) guidelines for the Treatment of HIV/AIDS.**
Local Service Category Definition/Services to be Provided:	**Outpatient/Ambulatory Primary Medical Care:** Services include on-site physician, physician extender, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication education, and patient care coordination. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral to appropriate medical provider upon primary care Physician's order). Services provided to women shall further include OB/GYN physician & physician extender services on-site or by referral, OB/GYN services, colposcopy, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication/women's health

	education, patient care coordination, and social services. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral protocols to appropriate agencies upon primary care Physician's order). **Outpatient/Ambulatory Primary Medical Care must provide:** • Continuity of care for all stages of adult HIV infection; • Laboratory and pharmacy services including intravenous medications (either on-site or through established referral systems); • Outpatient psychiatric care, including lab work necessary for the prescribing of psychiatric medications when appropriate (either on-site or through established referral systems); • Access to the Texas ADAP program (either on-site or through established referral systems); • Access to compassionate use HIV medication programs (either directly or through established referral systems); • Access to HIV related research protocols (either directly or through established referral systems); • Must at a minimum, comply with Houston EMA/HSDA Part A/B Standards for HIV Primary Medical Care. The Contractor must demonstrate on an ongoing basis the ability to provide state-of-the-art HIV-related primary care medicine in accordance with the most recent DHHS HIV treatment guidelines. Rapid advances in HIV treatment protocols require that the Contractor provide services that to the greatest extent possible maximize a patient's opportunity for long-term survival and maintenance of the highest quality of life possible. • On-site Outpatient Psychiatry services. • On-site Medical Case Management services. • On-site Medication Education. • Physical therapy services (either on-site or via referral). • Specialty Clinic Referrals (either on-site or via referral). • On-site pelvic exams as needed for female patients with appropriate follow-up treatment and referral. • On site Nutritional Counseling by a Licensed Dietitian. **Services for women must also provide:** • Well woman care, including but not limited to: PAP, pelvic exam, HPV screening, breast examination, mammography, hormone replacement and education, pregnancy testing, contraceptive services excluding birth control medications. • Obstetric Care: ante-partum through post-partum services, child birth/delivery services. Perinatal preventative education and treatment.

	• On-site or by referral Colposcopy exams as needed, performed by an OB/GYN physician, or physician extender with a colposcopy provider qualification. • Social services, including but not limited to, providing women access to child care, transportation vouchers, food vouchers and support groups at the clinic site. **Nutritional Assessment:** Services include provision of information about therapeutic nutritional/supplemental foods that are beneficial to the wellness and increased health conditions of clients by a Licensed Dietitian. Services may be provided either through educational or counseling sessions. Clients who receive these services may utilize the Ryan White Part A-funded nutritional supplement provider to obtain recommended nutritional supplements in accordance with program rules. Clients are limited to one (1) nutritional assessment per calendar year without prior approval of RWGA. Patient Medication Education Services must adhere to the following requirements: • Medication Educators must be State Licensed Medical Doctor (MD), Nurse Practitioner (NP), Physician Assistant PA), Nurse (RN, LVN) or Pharmacist. Prior approval must be obtained prior to utilizing any other health care professional not listed above to provide medication education. • Clients who will be prescribed ongoing medical regimens (i.e. ART) must be assessed for adherence to treatment at every clinical encounter using the EMA's approved adherence assessment tool. Clients with adherence issues related to lack of understanding must receive more education regarding their medical regimen. Clients with adherence issues that are behavioral or involve mental health issues must be provided counseling by the Medical Case Manager, Physician or Physician Extender and/or licensed nursing staff and, if clinically indicated, assessment and treatment by a qualified Psychiatrist or Psychiatric Nurse Practitioner. **Outpatient Psychiatric Services:** The program must provide: • Diagnostic Assessments: comprehensive evaluation for identification of psychiatric disorders, mental status evaluation, differential diagnosis which may involve use of other clinical and laboratory tests, case formulation, and treatment plans or disposition. • Emergency Psychiatric Services: rapid evaluation, differential diagnosis, acute treatment, crisis intervention, and referral. Must be available on a 24 hour basis including emergency room referral.

	• Brief Psychotherapy: individual, supportive, group, couple, family, hypnosis, biofeedback, and other psychophysiological treatments and behavior modification. • Psychopharmacotherapy: evaluation and medication treatment of psychiatric disorders, including, but not limited to, anxiety disorders, major depression, pain syndromes, habit control problems, psychosis and organic mental disorders. • Rehabilitation Services: Physical, psychosocial, behavioral, and/or cognitive training. Screening for Eye Disorders: Contractor must ensure that patients receive appropriate screening and treatment for CMV, glaucoma, cataracts, and other related problems. **Local Medication Assistance Program (LPAP):** LPAP provides pharmaceuticals to patients otherwise ineligible for medications through private insurance, Medicaid/Medicare, State ADAP, SPAP or other sources. Allowable medications are only those on the Houston EMA Ryan White Part A Formulary. Eligible clients may be provided Fuzeon™ on a case-by-case basis with prior approval of Ryan White Grant Administration (RWGA). The cost of Fuzeon™ does not count against a client's annual maximum. HIV-related medication services are the provision of physician or physician-extender prescribed HIV-related medications to prevent serious deterioration of health. Does not include drugs available to the patient from other programs or payers or free of charge (such as birth control and TB medications) or medications available over the counter (OTC) without prescription. Contractor must offer all medications on the Texas ADAP formulary, for a total not to exceed $18,000.00 per contract year per client. Contractor must provide allowable HIV-related medications (i.e. non-HIV medications) for a total not to exceed $3,000 per contract year per client. Contractor may be reimbursed ADAP dispensing fees (e.g. $5/Rx) in accordance with RWGA business rules for those ADAP clients who are unable to pay the ADAP dispensing fee. **Medical Case Management Services:** Services include screening all primary medical care patients to determine each patient's level of need for Medical Case Management services, performing a comprehensive assessment, including an assessment of the patient's health literary, and developing a medical service plan for each client that demonstrates a documented need for such services, monitoring medical service plan to ensure its implementation, and educating client regarding wellness, medication and health care appointment adherence. The Medical Case Manager serves as an advocate for the client and as a liaison with medical providers on behalf of the client. The Medical Case Manager ensures linkage to

	mental health, substance abuse and other client services as indicated by the medical service plan. **Service Linkage:** The purpose of Service Linkage is to assist clients with the procurement of needed services so that the problems associated with living with HIV are mitigated. Service Linkage is a working agreement between a client and a Service Linkage Worker for an indeterminate period, based on client need, during which information, referrals and service linkage are provided on an as-needed basis. Service Linkage assists clients who do not require the intensity of Medical Case Management per RWGA Quality Management guidelines. Service Linkage is both office-based and field based. Service Linkage Workers are expected to coordinate activities with referral sources where newly-diagnosed or not-in-care PLWHA may be identified, including 1:1 case conferences with testing site personnel to ensure the successful transition of referrals into Primary Care Services. Such incoming referral coordination includes meeting prospective clients at the referring Provider location in order to develop rapport with individuals prior to the individual's initial Primary Care appointment and ensuring such new intakes to Primary Care services have sufficient support to make the often difficult transition into ongoing primary medical care. Service Linkage also includes follow-up to re-engage lost-to-care patients. Lost-to-care patients are those patients who have not returned for scheduled appointments with Provider nor have provided Provider with updated information about their current Primary Medical Care provider (in the situation where patient may have obtained alternate service from another medical provider). Contractor must document efforts to re-engage lost-to-care patients prior to closing patients in the CPCDMS. Service Linkage extends the capability of existing programs by providing "hands-on" outreach and linkage to care services to those PLWHA who are not currently accessing primary medical care services. Service Linkage includes the issuance of bus pass vouchers and gas cards per published RWGA guidelines. Service Linkage complements and extends the service delivery capability of Medical Case Management services. **Outreach**: Providing allowable Ryan White Program outreach and service linkage activities to PLWHA who know their status but are not actively engaged in outpatient primary medical care with information, referrals and assistance with medical appointment setting, mental health, substance abuse and psychosocial services as needed; advocating on behalf of clients to decrease service gaps and remove barriers to services helping clients develop and utilize independent living skills and strategies. Assist clients in obtaining needed resources, including bus pass vouchers and gas cards per published HCPH/RWGA policies. Outreach services must be conducted at times and in places where there is a high probability

	that individuals with HIV infection will be contacted, designed to provide quantified program reporting of activities and outcomes to accommodate local evaluation of effectiveness, planned and delivered in coordination with local and state HIV prevention outreach programs to avoid duplication of effort, targeted to populations known, through review of clinic medical records, to be at disproportionate risk of disengagement with primary medical care services. **Emergency Financial Assistance – Pharmacy Assistance** provides limited one-time and/or short-term 30-day supply of pharmaceuticals to patients otherwise ineligible for medications through private insurance, Medicaid/Medicare, State ADAP, SPAP or other sources. One refill for up to 30-day supply available with RWGA prior approval. Allowable medications are only those on the Houston EMA Ryan White Part A Formulary. HIV-related medication services are the provision of physician or physician-extender prescribed medications to prevent serious deterioration of health. Does not include drugs available to the patient from other programs or payers or free of charge or medications available over the counter (OTC) without prescription. Contractor must offer all medications on the Texas ADAP formulary.
Agency Requirements:	**Providers and system must be Medicaid/Medicare certified.** **Eligibility and Benefits Coordination:** Contractor must implement consumer-friendly, culturally and linguistically appropriate new and ongoing patient eligibility verification and benefit coordination processes that ensure accountability with Ryan White Payer of Last Resort requirements while achieving maximum utilization of eligible benefits. Eligibility processes should provide clients with a meaningful understanding of their benefits, expected out-of-pocket expenses and other information needed to ensure full and continued participation in care. **LPAP and EFA – Pharmacy Assistance Services:** Contractor must: Provide pharmacy services on-site or through an established contractual relationship that meets all requirements. Alternate (off-site) approaches must be approved prior to implementation by RWGA. Either directly, or via subcontract with an eligible 340B Pharmacy program entity, must: Ensure a comprehensive financial intake application to determine client eligibility for this program to insure that these funds are used as a last resort for purchase of medications.

	Ensure the documented capability of interfacing with the Texas HIV Medication Program operated by the Texas Department of State Health Services. This capability must be fully documented and is subject to independent verification by RWGA. Ensure medication assistance provided to clients does not duplicate services already being provided in the Houston area. The process for accomplishing this must be fully documented and is subject to independent verification by RWGA. Ensure, either directly or via a 340B Pharmacy Program Provider, at least 2 years of continuous documented experience in providing HIV/AIDS medication programs utilizing Ryan White Program or similar public sector funding. This experience must be documented and is subject to independent verification by RWGA. Ensure all medications are purchased via a qualified participant in the federal 340B Drug Pricing Program and Prime Vendor Program, administered by the HRSA Office of Pharmacy Affairs. Note: failure to maintain 340B or Prime Vendor drug pricing may result in a negative audit finding, cost disallowance or termination of contract awarded. Contractor must maintain 340B Program participation throughout the contract term. All eligible medications must be purchased in accordance with Program 340B guidelines and program requirements. Ensure Houston area HIV/AIDS service providers are informed of this program and how the client referral and enrollment processes functions. Contractor must maintain documentation of such marketing efforts. Implement a consistent process to enroll eligible patients in available pharmaceutical company Patient Assistance Programs prior to using Ryan White Part A funded LPAP resources. Ensure information regarding the program is provided to PLWHA, including historically under-served and unserved populations (e.g., African American, Hispanic/Latino, Asian, Native American, Pacific Islander) and women not currently obtaining prescribed HIV and HIV-related medications. Offer, at no charge to the client, delivery options for medication refills, including but not limited to courier, USPS or other package delivery service. **Case Management Operations and Supervision:** The Service Linkage Workers (SLW) and Medical Case Managers (MCM) must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds published Standards of Care. An MCM may supervise SLWs.

Staff Requirements:	Contractor is responsible for ensuring that services are provided by State licensed internal medicine and OB/GYN physicians, specialty care physicians, psychiatrists, registered nurses, nurse practitioners, vocational nurses, pharmacists, physician assistants, clinical nurse specialists, physician extenders with a colposcopy provider qualification, x-ray technologists, State licensed dieticians, licensed social worker and ancillary health care providers in accordance with appropriate State licensing and/or certification requirements and with knowledge and experience of HIV disease. In addition, Contractor must ensure the following staff requirements are met: **Outpatient Psychiatric Services:** Director of the Program must be a Board Certified Psychiatrist. Licensed and/or Certified allied health professionals (Licensed Psychologists, Physicians, Psychiatric Nurse Practitioners, Licensed Master Social Workers, Licensed Professional Counselors, Licensed Marriage and Family Therapists, Certified Alcohol and Drug Abuse Counselors, etc.) must be used in all treatment modalities. Documentation of the Director's credentials, licensures and certifications must be included in the proposal. Documentation of the Allied Health professional licensures and certifications must be included in the proposal appendices. **Medication and Adherence Education:** The program must utilize an RN, LVN, PA, NP, pharmacist or MD licensed by the State of Texas, who has at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care, to provide the educational services. Licensed social workers who have at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care may also provide adherence education and counseling. **Nutritional Assessment (primary care):** Services must be provided by a licensed registered dietician. Dieticians must have a minimum of two (2) years of experience providing nutritional assessment and counseling to PLWHA. **Medical Case Management:** The program must utilize a state licensed Social Worker to provide Medical Case Management Services. The Contractor must maintain the assigned number of Medical Case Management FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Medical Case Manager and the individual assigned to supervise those Medical Case Managers within 30 days of start of grant year, and thereafter within 15 days after hire.** **Service Linkage:** The program must utilize Service Linkage Workers who have at a minimum a Bachelor's degree from an accredited college or university with a major in social or behavioral sciences. Documented paid work experience in providing client

	services to PLWHA may be substituted for the Bachelor's degree requirement on a 1:1 basis (1 year of documented paid experience may be substituted for 1 year of college). All Service Linkage Workers must have a minimum of one (1) year paid work experience with PLWHA. Contractor must maintain the assigned number of Service Linkage FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Service Linkage Worker and the individual assigned to supervise those Service Linkage Workers within 30 days of start of grant year, and thereafter within 15 days after hire.** **Supervision of Case Managers:** The Service Linkage Workers and Medical Case Managers must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds Houston EMA/HSDA Part A/B Standards of Care for Service Linkage and Medical Case Management as applicable. An MCM may supervise SLWs.
Special Requirements:	**All primary medical care services must meet or exceed current United States DHHS Treatment Guidelines for the treatment and management of HIV disease.** Contractor must provide all required program components - Primary Medical Care, Medical Case Management, Service Linkage (non-medical Case Management) and Local Pharmacy Assistance Program (LPAP) services. **Primary Medical Care Services:** Services funded under this grant cannot be used to supplant insurance or Medicare/Medicaid reimbursements for such services. Clients eligible for such reimbursement may not be billed to this contract. Medicare and private insurance co-payments may be eligible for reimbursement under Ryan White Health Insurance Assistance (HINS) program guidelines. Patients needing such assistance should be referred to the local Ryan White-funded HINS provider for assistance. Under no circumstances may the Contractor bill the County for the difference between the reimbursement from Medicaid, Medicare or Third Party insurance and the fee schedule under the contract. Furthermore, potential clients who are Medicaid/Medicare eligible or have other Third Party payers may not be denied services or referred elsewhere by the Contractor based on their reimbursement status (i.e. Medicaid/Medicare eligible clients may not be referred elsewhere in order that non-Medicaid/Medicare eligible clients may be added to the contract). Failure to serve Medicaid/Medicare eligible clients based on their reimbursement status will be grounds for the immediate termination of contract.

	For primary medical care services targeted to the Latino community at least 50% of the clinical care team must be fluent in Spanish. **Diagnostic Procedures:** A single Diagnostic Procedure limited to procedures on the approved list of diagnostic procedures (see below) without prior County approval. Approved diagnostic procedures will be reimbursed at invoice cost. Part A and Part A/MAI-funded programs must refer to the RWGA website for the most current list of approved diagnostic procedures and corresponding codes: www.hcphes.org/rwga. **Diagnostic procedures not listed on the website must have prior approval by RWGA.** **Outpatient Psychiatric Services:** Client must not be eligible for services from other programs/providers or any other reimbursement source (i.e. Medicaid, Medicare, private insurance) unless the client is in crisis and cannot be provided immediate services from the other programs/providers. In this case, clients may be provided services, as long as the client applies for the other programs/providers, until the other programs/providers can take over services. Program must be supervised by a Psychiatrist and include diagnostic assessments, emergency evaluations and psycho-pharmacotherapy. **Maintaining Referral Relationships** (Point of Entry Agreements): Contractor must maintain appropriate relationships with entities that constitute key points of access to the health care system for individuals with HIV disease, including but not limited to, Harris Health System and other Houston EMA-located emergency rooms, Harris County Jail, Texas Department of Criminal Justice incarceration facilities, Immigration detention centers, substance abuse treatment and detoxification programs, adult and juvenile detention facilities, Sexually Transmitted Disease clinics, federally qualified health centers (FQHC), HIV disease counseling and testing sites, mental health programs and homeless shelters. These referral relationships must be documented with written collaborative agreements, contracts or memoranda of understanding between Contractor and appropriate point of entry entities and are subject to audit by RWGA. Contractor and POE entity staff must regularly (e.g. weekly, bi-weekly depending on volume of referrals) meet 1:1 to discuss new referrals to primary medical care services. Such case conferences must be documented in the client record and properly entered into the CPCDMS. Use of CPCDMS Data System: Contractor must comply with CPCDMS business rules and procedures. Contractor must enter into the CPCDMS all required clinical data, including but not limited to, HAART treatment including all changes in medication

	regimens, Opportunistic Infections, screening and treatment for STDs and Hepatitis A, B, C and other clinical screening and treatment data required by HRSA, TDSHS and the County. Contractor must perform Registration updates in accordance with RWGA CPCDMS business rules for all clients wherein Contractor is client's CPCDMS record-owning agency. Contractor must utilize an electronic verification system to verify insurance/3rd party payer status monthly or per visit (whichever is less frequent). **Bus Pass Distribution:** The County will provide Contractor with METRO bus pass vouchers. Bus Pass vouchers must be distributed in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Contractor may only issue METRO bus pass vouchers to clients wherein the Contractor is the CPCDMS record owning Contractor. METRO bus pass vouchers shall be distributed as follows: **Expiration of Current Bus Pass:** In those situation wherein the bus pass expiration date does not coincide with the CPCDMS registration update the Contractor must distribute METRO bus pass vouchers to eligible clients upon the expiration of the current bus pass or when a Value-based bus card has been expended on eligible transportation needs. Contractor may issue METRO bus passes to eligible clients living outside the METRO service area in those situations where the Contractor has documented in the client record that the client will utilize the METRO system to access needed HIV-related health care services located in the METRO service area. **Gas Cards:** Primary Medical Care Contractors must distribute gasoline vouchers to eligible clients residing in the rural service area in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Gas Cards are only available to Rural primary medical care Contractors without prior approval by RWGA.

FY 2022 RWPC "How to Best Meet the Need" Decision Process

Step in Process: **Council**		Date: **06/10/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Steering Committee**		Date: **06/03/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Quality Improvement Committee**		Date: **05/18/2021**
Recommendations:	Approved: Y:_ ___ No: _____ Approved With Changes: _____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **HTBMTN Workgroup #1**	Date: **04/20/2021**
Recommendations:	Financial Eligibility:
1.	
2.	
3.	

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HRSA Service Category Title: **RWGA Only**	1. Outpatient/Ambulatory Medical Care 2. Medical Case Management 3. AIDS Pharmaceutical Assistance (local) 4. Case Management (non-Medical) 5. Emergency Financial Assistance – Pharmacy Assistance 6. Outreach
Local Service Category Title:	Adult Comprehensive Primary Medical Care i. Targeted to Public Clinic ii. Targeted to Women at Public Clinic
Amount Available: **RWGA Only**	Total estimated available funding: $0.00 (to be determined) 1. Primary Medical Care: $0.00 (including MAI) i. Targeted to Public Clinic: $0.00 ii. Targeted to Women at Public Clinic: $0.00 2. LPAP $0.00 3. Medical Case Management: $0.00 i. Targeted to Public Clinic: $0.00 ii. Targeted to Women at Public Clinic: $0.00 4. Service Linkage: $0.00 Note: The Houston Ryan White Planning Council (RWPC) determines annual Part A and MAI service category allocations & reallocations. RWGA has sole authority over contract award amounts.
Target Population:	Comprehensive Primary Medical Care – Community Based i. Targeted to Public Clinic ii. Targeted to Women at Public Clinic **Outreach:** Services will be available to eligible HIV-infected clients residing in the Houston EMA/HSDA with priority given to clients most in need. Services are restricted to those clients who meet the contractor's RWGA approved Outreach Inclusion Criteria. The Outreach Inclusion Criteria components must include, at minimum 2 consecutive missed primary care provider and/or HIV lab appointments. Outreach Inclusion Criteria may also include VL suppression, substance abuse, and ART treatment failure components.

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Financial Eligibility:	*See Current Year Approved Financial Eligibility for Houston EMA/HSDA*
Budget Type: **RWGA Only**	Hybrid Fee for Service
Budget Requirement or Restrictions: **RWGA Only**	**Primary Medical Care:** 100% of clients served under the *Targeted to Women at Public Clinic* subcategory must be female 10% of funds designated to primary medical care must be reserved for invoicing diagnostic procedures at actual cost. Contractors may not exceed the allocation for each individual service component (Primary Medical Care, Medical Case Management, Local Pharmacy Assistance Program and Service Linkage) without prior approval from RWGA. **Local Pharmacy Assistance Program (LPAP):** Houston RWPC guidelines for Local Pharmacy Assistance Program (LPAP) services: Contractor shall offer HIV medications from an approved formulary for a total not to exceed $18,000 per contract year per client. Contractor shall offer HIV-related medications for a total not to exceed $3,000 per contract year per client. These guidelines are determined by the RWPC. The RWPC determines the subcategories that shall include Ryan White LPAP funding. Medications must be provided in accordance with Houston EMA guidelines, HRSA/HAB rules and regulations and applicable Office of Pharmacy Affairs 340B guidelines. At least 75% of the total amount of the budget for LPAP services must be solely allocated to the actual cost of medications and may not include any storage, administrative, processing or other costs associated with managing the medication inventory or distribution. **Emergency Financial Assistance – Pharmacy Assistance** Direct cash payments to clients are not permitted. It is expected that all other sources of funding in the community for emergency financial assistance will be effectively used and that any allocation of RWHAP funds for these purposes will be as the payer of last

	resort, and for limited amounts, uses, and periods of time. Continuous provision of an allowable service to a client should not be funded through emergency financial assistance. **Outreach** Outreach services are restricted to those patients who have not returned for scheduled appointments with Provider as outlined in the RWGA approved Outreach Inclusion Criteria, and are included on the Outreach list.
Service Unit Definition/s: **RWGA Only**	• Outpatient/Ambulatory Medical Care: One (1) unit of service = One (1) primary care office/clinic visit which includes the following: • Primary care physician/nurse practitioner, physician's assistant or clinical nurse specialist examination of the patient, and • Medication/treatment education • Medication access/linkage • OB/GYN specialty procedures (as clinically indicated) • Nutritional assessment (as clinically indicated) • Laboratory (as clinically indicated, not including specialized tests) • Radiology (as clinically indicated, not including CAT scan or MRI) • Eligibility verification/screening (as necessary) • Follow-up visits wherein the patient is not seen by the MD/NP/PA are considered to be a component of the original primary care visit. • Outpatient Psychiatric Services: 1 unit of service = A single (1) office/clinic visit wherein the patient is seen by a State licensed and board-eligible Psychiatrist or qualified Psychiatric Nurse Practitioner. This visit may or may not occur on the same date as a primary care office visit. • Medication Education: 1 unit of service = A single pharmacy visit wherein a Ryan White eligible client is provided medication education services by a qualified pharmacist. This visit may or may not occur on the same date as a primary care office visit. Maximum reimbursement allowable for a medication education visit may not exceed $50.00 per visit. The visit must include at least one prescription medication being provided to clients. A maximum of one (1) Medication Education Visit may be provided to an individual client per day, regardless of the number of prescription medications provided. • Nutritional Assessment and Plan: 1 unit of service = A single comprehensive nutritional assessment and treatment plan performed by a Licensed, Registered Dietician initiated upon a physician's order. Does not include the provision of Supplements or other products (clients may be referred to the

	Ryan White funded Medical Nutritional Therapy provider for provision of medically necessary supplements). The nutritional assessment visit may or may not occur on the same date as a medical office visit. • AIDS Pharmaceutical Assistance (local): A unit of service = a transaction involving the filling of a prescription or any other allowable medication need ordered by a qualified medical practitioner. The transaction will involve at least one item being provided for the client, but can be any multiple. The cost of medications provided to the client must be invoiced at actual cost. • Medical Case Management: 1 unit of service = 15 minutes of direct medical case management services to an eligible PLWHA performed by a qualified medical case manager. • Service Linkage (non-Medical Case Management): 1 unit of service = 15 minutes of direct service linkage services to an eligible PLWHA performed by a qualified service linkage worker. • Outreach: 15 Minutes = 1 Unit • Emergency Financial Assistance – Pharmacy Assistance: A unit of service = a transaction involving the filling of a prescription or any other allowable HIV treatment medication need ordered by a qualified medical practitioner. The transaction will involve at least one item being provided for the client, but can be any multiple. The cost of medications provided to the client must be invoiced at actual cost.
HRSA Service Category Definition: **RWGA Only**	• **Outpatient/Ambulatory medical care** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). Primary medical care for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service's guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies. • **AIDS Pharmaceutical Assistance (local)** includes local pharmacy assistance programs implemented by Part A or Part

	B Grantees to provide HIV/AIDS medications to clients. This assistance can be funded with Part A grant funds and/or Part B base award funds. Local pharmacy assistance programs are not funded with ADAP earmark funding. • **Medical Case Management** services (including treatment adherence) are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication. • **Case Management (non-Medical)** includes the provision of advice and assistance in obtaining medical, social, community, legal, financial, and other needed services. Non-medical case management does not involve coordination and follow-up of medical treatments, as medical case management does. • **Emergency Financial Assistance** provides limited one-time or short-term payments to assist the RWHAP client with an emergent need for paying for essential utilities, housing, food (including groceries, and food vouchers), transportation, and medication. Emergency financial assistance can occur as a direct payment to an agency or through a voucher program. • **Outreach Services** include the provision of the following three activities: Identification of people who do not know their HIV status and linkage into Outpatient/Ambulatory Health Services, Provision of additional information and education on health care coverage options, Reengagement of people who know their status into Outpatient/Ambulatory Health Services
Standards of Care:	Contractors must adhere to the most current published Part A/B Standards of Care for the Houston EMA/HSDA. **Services must meet or exceed applicable United States Department of Health and Human Services (DHHS) guidelines for the Treatment of HIV/AIDS.**

Local Service Category Definition/Services to be Provided:	**Outpatient/Ambulatory Primary Medical Care:** Services include on-site physician, physician extender, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication education, and patient care coordination. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral to appropriate medical provider upon primary care Physician's order). Services provided to women shall further include OB/GYN physician & physician extender services on-site or by referral, OB/GYN services, colposcopy, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication/women's health education, patient care coordination, and social services. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral protocols to appropriate agencies upon primary care Physician's order). **Outpatient/Ambulatory Primary Medical Care must provide:** • Continuity of care for all stages of adult HIV infection; • Laboratory and pharmacy services including intravenous medications (either on-site or through established referral systems); • Outpatient psychiatric care, including lab work necessary for the prescribing of psychiatric medications when appropriate (either on-site or through established referral systems); • Access to the Texas ADAP program (either on-site or through established referral systems); • Access to compassionate use HIV medication programs (either directly or through established referral systems); • Access to HIV related research protocols (either directly or through established referral systems); • Must at a minimum, comply with Houston EMA/HSDA Part A/B Standards for HIV Primary Medical Care. The Contractor must demonstrate on an ongoing basis the ability to provide state-of-the-art HIV-related primary care medicine in accordance with the most recent DHHS HIV treatment guidelines. Rapid advances in HIV treatment protocols require that the Contractor provide services that to the greatest extent possible maximize a patient's opportunity for long-term survival and maintenance of the highest quality of life possible. • On-site Outpatient Psychiatry services. • On-site Medical Case Management services. • On-site Medication Education. • Physical therapy services (either on-site or via referral). • Specialty Clinic Referrals (either on-site or via referral).

	• On-site pelvic exams as needed for female patients with appropriate follow-up treatment and referral. • On site Nutritional Counseling by a Licensed Dietitian. **Women's Services must also provide:** • Well woman care, including but not limited to: PAP, pelvic exam, HPV screening, breast examination, mammography, hormone replacement and education, pregnancy testing, contraceptive services excluding birth control medications. • Obstetric Care: ante-partum through post-partum services, child birth/delivery services. Perinatal preventative education and treatment. • On-site or by referral Colposcopy exams as needed, performed by an OB/GYN physician, or physician extender with a colposcopy provider qualification. • Social services, including but not limited to, providing women access to child care, transportation vouchers, food vouchers and support groups at the clinic site; **Nutritional Assessment:** Services include provision of information about therapeutic nutritional/supplemental foods that are beneficial to the wellness and increased health conditions of clients by a Licensed Dietitian. Services may be provided either through educational or counseling sessions. Clients who receive these services may utilize the Ryan White Part A-funded nutritional supplement provider to obtain recommended nutritional supplements in accordance with program rules. Clients are limited to one (1) nutritional assessment per calendar year without prior approval of RWGA. Patient Medication Education Services must adhere to the following requirements: • Medication Educators must be State Licensed Medical Doctor (MD), Nurse Practitioner (NP), Physician Assistant PA), Nurse (RN, LVN) or Pharmacist. Prior approval must be obtained prior to utilizing any other health care professional not listed above to provide medication education. • Clients who will be prescribed ongoing medical regimens (i.e. ART) must be assessed for adherence to treatment at every clinical encounter using the EMA's approved adherence assessment tool. Clients with adherence issues related to lack of understanding must receive more education regarding their medical regimen. Clients with adherence issues that are behavioral or involve mental health issues must be provided counseling by the Medical Case Manager, Physician or Physician Extender and/or licensed nursing staff and, if

	clinically indicated, assessment and treatment by a qualified Psychiatrist or Psychiatric Nurse Practitioner. **Outpatient Psychiatric Services:** The program must provide: • Diagnostic Assessments: comprehensive evaluation for identification of psychiatric disorders, mental status evaluation, differential diagnosis which may involve use of other clinical and laboratory tests, case formulation, and treatment plans or disposition. • Emergency Psychiatric Services: rapid evaluation, differential diagnosis, acute treatment, crisis intervention, and referral. Must be available on a 24 hour basis including emergency room referral. • Brief Psychotherapy: individual, supportive, group, couple, family, hypnosis, biofeedback, and other psychophysiological treatments and behavior modification. • Psychopharmacotherapy: evaluation and medication treatment of psychiatric disorders, including, but not limited to, anxiety disorders, major depression, pain syndromes, habit control problems, psychosis and organic mental disorders. • Rehabilitation Services: Physical, psychosocial, behavioral, and/or cognitive training. Screening for Eye Disorders: Contractor must ensure that patients receive appropriate screening and treatment for CMV, glaucoma, cataracts, and other related problems. **Local Medication Assistance Program (LPAP):** LPAP provides pharmaceuticals to patients otherwise ineligible for medications through private insurance, Medicaid/Medicare, State ADAP, SPAP or other sources. Allowable medications are only those on the Houston EMA Ryan White Part A Formulary. Eligible clients may be provided Fuzeon™ on a case-by-case basis with prior approval of Ryan White Grant Administration (RWGA). The cost of Fuzeon™ does not count against a client's annual maximum. HIV-related medication services are the provision of physician or physician-extender prescribed HIV-related medications to prevent serious deterioration of health. Does not include drugs available to the patient from other programs or payers or free of charge (such as birth control and TB medications) or medications available over the counter (OTC) without prescription. Contractor must offer all medications on the Texas ADAP formulary, for a total not to exceed $18,000.00 per contract year per client. Contractor must provide allowable HIV-related medications (i.e. non-HIV medications) for a total not to exceed $3,000 per contract year per client. Contractor may be reimbursed ADAP

	dispensing fees (e.g. $5/Rx) in accordance with RWGA business rules for those ADAP clients who are unable to pay the ADAP dispensing fee. **Medical Case Management Services:** Services include screening all primary medical care patients to determine each patient's level of need for Medical Case Management services, performing a comprehensive assessment, including an assessment of the patient's health literary, and developing a medical service plan for each client that demonstrates a documented need for such services, monitoring medical service plan to ensure its implementation, and educating client regarding wellness, medication and health care appointment adherence. The Medical Case Manager serves as an advocate for the client and as a liaison with medical providers on behalf of the client. The Medical Case Manager ensures linkage to mental health, substance abuse and other client services as indicated by the medical service plan. **Service Linkage:** The purpose of Service Linkage is to assist clients with the procurement of needed services so that the problems associated with living with HIV are mitigated. Service Linkage is a working agreement between a client and a Service Linkage Worker for an indeterminate period, based on client need, during which information, referrals and service linkage are provided on an as-needed basis. Service Linkage assists clients who do not require the intensity of Medical Case Management per RWGA Quality Management guidelines. Service Linkage is both office-based and field based. Service Linkage Workers are expected to coordinate activities with referral sources where newly-diagnosed or not-in-care PLWHA may be identified, including 1:1 case conferences with testing site personnel to ensure the successful transition of referrals into Primary Care Services. Such incoming referral coordination includes meeting prospective clients at the referring Provider location in order to develop rapport with individuals prior to the individual's initial Primary Care appointment and ensuring such new intakes to Primary Care services have sufficient support to make the often difficult transition into ongoing primary medical care. Service Linkage also includes follow-up to re-engage lost-to-care patients. Lost-to-care patients are those patients who have not returned for scheduled appointments with Provider nor have provided Provider with updated information about their current Primary Medical Care provider (in the situation where patient may have obtained alternate service from another medical provider). Contractor must document efforts to re-engage lost-to-care patients prior to closing patients in the CPCDMS. Service Linkage extends the capability of existing programs by providing "hands-on" outreach and linkage to care services to those PLWHA who are not currently accessing primary medical care services. Service Linkage includes the issuance of

	bus pass vouchers and gas cards per published RWGA guidelines. Service Linkage complements and extends the service delivery capability of Medical Case Management services. **Outreach**: Providing allowable Ryan White Program outreach and service linkage activities to PLWHA who know their status but are not actively engaged in outpatient primary medical care with information, referrals and assistance with medical appointment setting, mental health, substance abuse and psychosocial services as needed; advocating on behalf of clients to decrease service gaps and remove barriers to services helping clients develop and utilize independent living skills and strategies. Assist clients in obtaining needed resources, including bus pass vouchers and gas cards per published HCPH/RWGA policies. Outreach services must be conducted at times and in places where there is a high probability that individuals with HIV infection will be contacted, designed to provide quantified program reporting of activities and outcomes to accommodate local evaluation of effectiveness, planned and delivered in coordination with local and state HIV prevention outreach programs to avoid duplication of effort, targeted to populations known, through review of clinic medical records, to be at disproportionate risk of disengagement with primary medical care services. **Emergency Financial Assistance – Pharmacy Assistance** provides limited one-time and/or short-term 30-day supply of pharmaceuticals to patients otherwise ineligible for medications through private insurance, Medicaid/Medicare, State ADAP, SPAP or other sources. One refill for up to 30-day supply available with RWGA prior approval. Allowable medications are only those on the Houston EMA Ryan White Part A Formulary. HIV-related medication services are the provision of physician or physician-extender prescribed medications to prevent serious deterioration of health. Does not include drugs available to the patient from other programs or payers or free of charge or medications available over the counter (OTC) without prescription. Contractor must offer all medications on the Texas ADAP formulary.
Agency Requirements:	**Providers and system must be Medicaid/Medicare certified.** **Eligibility and Benefits Coordination:** Contractor must implement consumer-friendly, culturally and linguistically appropriate new and ongoing patient eligibility verification and benefit coordination processes that ensure accountability with Ryan White Payer of Last Resort requirements while achieving maximum utilization of eligible benefits. Eligibility processes should provide clients with a meaningful understanding of their benefits, expected out-of-pocket expenses and other information needed to ensure full and continued participation in care.

	LPAP and EFA – Pharmacy Assistance Services: Contractor must: Provide pharmacy services on-site or through an established contractual relationship that meets all requirements. Alternate (off-site) approaches must be approved prior to implementation by RWGA. Either directly, or via subcontract with an eligible 340B Pharmacy program entity, must: Ensure a comprehensive financial intake application to determine client eligibility for this program to insure that these funds are used as a last resort for purchase of medications. Ensure the documented capability of interfacing with the Texas HIV Medication Program operated by the Texas Department of State Health Services. This capability must be fully documented and is subject to independent verification by RWGA. Ensure medication assistance provided to clients does not duplicate services already being provided in the Houston area. The process for accomplishing this must be fully documented and is subject to independent verification by RWGA. Ensure, either directly or via a 340B Pharmacy Program Provider, at least 2 years of continuous documented experience in providing HIV/AIDS medication programs utilizing Ryan White Program or similar public sector funding. This experience must be documented and is subject to independent verification by RWGA. Ensure all medications are purchased via a qualified participant in the federal 340B Drug Pricing Program and Prime Vendor Program, administered by the HRSA Office of Pharmacy Affairs. Note: failure to maintain 340B or Prime Vendor drug pricing may result in a negative audit finding, cost disallowance or termination of contract awarded. Contractor must maintain 340B Program participation throughout the contract term. All eligible medications must be purchased in accordance with Program 340B guidelines and program requirements. Ensure Houston area HIV/AIDS service providers are informed of this program and how the client referral and enrollment processes functions. Contractor must maintain documentation of such marketing efforts. Implement a consistent process to enroll eligible patients in available pharmaceutical company Patient Assistance Programs prior to using Ryan White Part A funded LPAP resources.

	Ensure information regarding the program is provided to PLWHA, including historically under-served and unserved populations (e.g., African American, Hispanic/Latino, Asian, Native American, Pacific Islander) and women not currently obtaining prescribed HIV and HIV-related medications. Offer, at no charge to the client, delivery options for medication refills, including but not limited to courier, USPS or other package delivery service. **Case Management Operations and Supervision:** The Service Linkage Workers (SLW) and Medical Case Managers (MCM) must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds published Standards of Care. An MCM may supervise SLWs.
Staff Requirements:	Contractor is responsible for ensuring that services are provided by State licensed internal medicine and OB/GYN physicians, specialty care physicians, psychiatrists, registered nurses, nurse practitioners, vocational nurses, pharmacists, physician assistants, clinical nurse specialists, physician extenders with a colposcopy provider qualification, x-ray technologists, State licensed dieticians, licensed social worker and ancillary health care providers in accordance with appropriate State licensing and/or certification requirements and with knowledge and experience of HIV disease. In addition, Contractor must ensure the following staff requirements are met: **Outpatient Psychiatric Services:** Director of the Program must be a Board Certified Psychiatrist. Licensed and/or Certified allied health professionals (Licensed Psychologists, Physicians, Psychiatric Nurse Practitioners, Licensed Master Social Workers, Licensed Professional Counselors, Licensed Marriage and Family Therapists, Certified Alcohol and Drug Abuse Counselors, etc.) must be used in all treatment modalities. Documentation of the Director's credentials, licensures and certifications must be included in the proposal. Documentation of the Allied Health professional licensures and certifications must be included in the proposal appendices. **Medication and Adherence Education:** The program must utilize an RN, LVN, PA, NP, pharmacist or MD licensed by the State of Texas, who has at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care, to provide the educational services. Licensed social workers who have at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care may also provide adherence education and counseling. **Nutritional Assessment (primary care):** Services must be provided by a licensed registered dietician. Dieticians must have a

	minimum of two (2) years of experience providing nutritional assessment and counseling to PLWHA. **Medical Case Management:** The program must utilize a state licensed Social Worker to provide Medical Case Management Services. The Contractor must maintain the assigned number of Medical Case Management FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Medical Case Manager and the individual assigned to supervise those Medical Case Managers by 03/30/15, and thereafter within 15 days after hire.** **Service Linkage:** The program must utilize Service Linkage Workers who have at a minimum a Bachelor's degree from an accredited college or university with a major in social or behavioral sciences. Documented paid work experience in providing client services to PLWHA may be substituted for the Bachelor's degree requirement on a 1:1 basis (1 year of documented paid experience may be substituted for 1 year of college). All Service Linkage Workers must have a minimum of one (1) year paid work experience with PLWHA. Contractor must maintain the assigned number of Service Linkage FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Service Linkage Worker and the individual assigned to supervise those Service Linkage Workers by 03/30/15, and thereafter within 15 days after hire.** **Supervision of Case Managers:** The Service Linkage Workers and Medical Case Managers must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds Houston EMA/HSDA Part A/B Standards of Care for Service Linkage and Medical Case Management as applicable. An MCM may supervise SLWs.

Special Requirements: **RWGA Only**	**All primary medical care services must meet or exceed current United States DHHS Treatment Guidelines for the treatment and management of HIV disease.** Contractor must provide all required program components - Primary Medical Care, Medical Case Management, Service Linkage (non-medical Case Management) and Local Pharmacy Assistance Program (LPAP) services. **Primary Medical Care Services:** Services funded under this grant cannot be used to supplant insurance or Medicare/Medicaid reimbursements for such services. Clients eligible for such reimbursement may not be billed to this contract. Medicare and private insurance co-payments may be eligible for reimbursement under Ryan White Health Insurance Assistance (HINS) program guidelines. Patients needing such assistance should be referred to the local Ryan White-funded HINS provider for assistance. Under no circumstances may the Contractor bill the County for the difference between the reimbursement from Medicaid, Medicare or Third Party insurance and the fee schedule under the contract. Furthermore, potential clients who are Medicaid/Medicare eligible or have other Third Party payers may not be denied services or referred elsewhere by the Contractor based on their reimbursement status (i.e. Medicaid/Medicare eligible clients may not be referred elsewhere in order that non-Medicaid/Medicare eligible clients may be added to the contract). Failure to serve Medicaid/Medicare eligible clients based on their reimbursement status will be grounds for the immediate termination of contract. **Diagnostic Procedures:** A single Diagnostic Procedure limited to procedures on the approved list of diagnostic procedures (see below) without prior County approval. Approved diagnostic procedures will be reimbursed at invoice cost. Part A and Part A/MAI-funded programs must refer to the RWGA website for the most current list of approved diagnostic procedures and corresponding codes: www.hcphes.org/rwga. **Diagnostic procedures not listed on the website must have prior approval by RWGA.** **Outpatient Psychiatric Services:** Client must not be eligible for services from other programs/providers or any other reimbursement source (i.e. Medicaid, Medicare, private insurance) unless the client is in crisis and cannot be provided immediate services from the other programs/providers. In this case, clients may be provided services, as long as the client applies for the other programs/providers, until the other programs/providers can take over services. Program must be supervised by a Psychiatrist and

include diagnostic assessments, emergency evaluations and psycho-pharmacotherapy.

Maintaining Referral Relationships (Point of Entry Agreements): Contractor must maintain appropriate relationships with entities that constitute key points of access to the health care system for individuals with HIV disease, including but not limited to, Harris Health System and other Houston EMA-located emergency rooms, Harris County Jail, Texas Department of Criminal Justice incarceration facilities, Immigration detention centers, substance abuse treatment and detoxification programs, adult and juvenile detention facilities, Sexually Transmitted Disease clinics, federally qualified health centers (FQHC), HIV disease counseling and testing sites, mental health programs and homeless shelters. These referral relationships must be documented with written collaborative agreements, contracts or memoranda of understanding between Contractor and appropriate point of entry entities and are subject to audit by RWGA. Contractor and POE entity staff must regularly (e.g. weekly, bi-weekly depending on volume of referrals) meet 1:1 to discuss new referrals to primary medical care services. Such case conferences must be documented in the client record and properly entered into the CPCDMS.

Use of CPCDMS Data System: Contractor must comply with CPCDMS business rules and procedures. Contractor must enter into the CPCDMS all required clinical data, including but not limited to, HAART treatment including all changes in medication regimens, Opportunistic Infections, screening and treatment for STDs and Hepatitis A, B, C and other clinical screening and treatment data required by HRSA, TDSHS and the County. Contractor must perform Registration updates in accordance with RWGA CPCDMS business rules for all clients wherein Contractor is client's CPCDMS record-owning agency. Contractor must utilize an electronic verification system to verify insurance/3rd party payer status monthly or per visit (whichever is less frequent).

Bus Pass Distribution: The County will provide Contractor with METRO bus pass vouchers. Bus Pass vouchers must be distributed in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Contractor may only issue METRO bus pass vouchers to clients wherein the Contractor is the CPCDMS record owning Contractor. METRO bus pass vouchers shall be distributed as follows:

Expiration of Current Bus Pass: In those situation wherein the bus pass expiration date does not coincide with the CPCDMS registration update the Contractor must distribute METRO bus pass vouchers to eligible clients upon the expiration of the current bus pass or when a Value-based bus card has been expended on eligible

	transportation needs. Contractor may issue METRO bus passes to eligible clients living outside the METRO service area in those situations where the Contractor has documented in the client record that the client will utilize the METRO system to access needed HIV-related health care services located in the METRO service area. **Gas Cards:** Primary Medical Care Contractors must distribute gasoline vouchers to eligible clients residing in the rural service area in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Gas Cards are only available to Rural primary medical care Contractors without prior approval by RWGA.

FY 2022 RWPC "How to Best Meet the Need" Decision Process

Step in Process: **Council**		Date: **06/10/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Steering Committee**		Date: **06/03/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Quality Improvement Committee**		Date: **05/18/2021**
Recommendations:	Approved: Y:_ ___ No: _____ Approved With Changes: _____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **HTBMTN Workgroup #1**	Date: **04/20/2021**
Recommendations:	Financial Eligibility:
1.	
2.	
3.	

FY 2020 Houston EMA Ryan White Part A/MAI Service Definition **Comprehensive Outpatient Primary Medical Care including Medical Case Management, Service Linkage and Local Pharmacy Assistance Program (LPAP) Services - Rural**	
HRSA Service Category Title: **RWGA Only**	1. Outpatient/Ambulatory Medical Care 2. Medical Case Management 3. AIDS Pharmaceutical Assistance (local) 4. Emergency Financial Assistance – Pharmacy Assistance 5. Case Management (non-Medical)
Local Service Category Title:	Adult Comprehensive Primary Medical Care - Targeted to Rural
Amount Available: **RWGA Only**	Total estimated available funding: $0.00 (to be determined) 1. Primary Medical Care: $0.00 2. LPAP $0.00 3. Medical Case Management: $0.00 4. Service Linkage: $0.00 Note: The Houston Ryan White Planning Council (RWPC) determines overall annual Part A and MAI service category allocations & reallocations. RWGA has sole authority over contract award amounts.
Target Population:	Comprehensive Primary Medical Care – Targeted to Rural
Client Eligibility: Age, Gender, Race, Ethnicity, Residence, etc.	PLWHA residing in the Houston EMA/HSDA counties **other than Harris County** (prior approval required for non-EMA clients). Contractor must adhere to Targeting requirements and Budget limitations as applicable.
Financial Eligibility:	*See Current Year Approved Financial Eligibility for Houston EMA/HSDA*
Budget Type: **RWGA Only**	Hybrid Fee for Service
Budget Requirement or Restrictions: **RWGA Only**	**Primary Medical Care:** No less than 75% of clients served in a Targeted subcategory must be members of the targeted population with the following exceptions: 10% of funds designated to primary medical care must be reserved for invoicing diagnostic procedures at actual cost. Contractors may not exceed the allocation for each individual service component (Primary Medical Care, Medical Case Management, Local Pharmacy Assistance Program and Service Linkage) without prior approval from RWGA.

	Local Pharmacy Assistance Program (LPAP): Houston RWPC guidelines for Local Pharmacy Assistance Program (LPAP) services: Contractor shall offer HIV medications from an approved formulary for a total not to exceed $18,000 per contract year per client. Contractor shall offer HIV-related medications for a total not to exceed $3,000 per contract year per client. These guidelines are determined by the RWPC. The RWPC determines the subcategories that shall include Ryan White LPAP funding. Medications must be provided in accordance with Houston EMA guidelines, HRSA/HAB rules and regulations and applicable Office of Pharmacy Affairs 340B guidelines. At least 75% of the total amount of the budget for LPAP services must be solely allocated to the actual cost of medications and may not include any storage, administrative, processing or other costs associated with managing the medication inventory or distribution. **Emergency Financial Assistance – Pharmacy Assistance** Direct cash payments to clients are not permitted. It is expected that all other sources of funding in the community for emergency financial assistance will be effectively used and that any allocation of RWHAP funds for these purposes will be as the payer of last resort, and for limited amounts, uses, and periods of time. Continuous provision of an allowable service to a client should not be funded through emergency financial assistance.
Service Unit Definition/s:	• Outpatient/Ambulatory Medical Care: One (1) unit of service = One (1) primary care office/clinic visit which includes the following: • Primary care physician/nurse practitioner, physician's assistant or clinical nurse specialist examination of the patient, and • Medication/treatment education • Medication access/linkage • OB/GYN specialty procedures (as clinically indicated) • Nutritional assessment (as clinically indicated) • Laboratory (as clinically indicated, not including specialized tests) • Radiology (as clinically indicated, not including CAT scan or MRI) • Eligibility verification/screening (as necessary)

	• Follow-up visits wherein the patient is not seen by the MD/NP/PA are considered to be a component of the original primary care visit. • Outpatient Psychiatric Services: 1 unit of service = A single (1) office/clinic visit wherein the patient is seen by a State licensed and board-eligible Psychiatrist or qualified Psychiatric Nurse Practitioner. This visit may or may not occur on the same date as a primary care office visit. • Nutritional Assessment and Plan: 1 unit of service = A single comprehensive nutritional assessment and treatment plan performed by a Licensed, Registered Dietician initiated upon a physician's order. Does not include the provision of Supplements or other products (clients may be referred to the Ryan White funded Medical Nutritional Therapy provider for provision of medically necessary supplements). The nutritional assessment visit may or may not occur on the same date as a medical office visit. • AIDS Pharmaceutical Assistance (local): A unit of service = a transaction involving the filling of a prescription or any other allowable medication need ordered by a qualified medical practitioner. The transaction will involve at least one item being provided for the client, but can be any multiple. The cost of medications provided to the client must be invoiced at actual cost. • Medical Case Management: 1 unit of service = 15 minutes of direct medical case management services to an eligible PLWHA performed by a qualified medical case manager. • Service Linkage (non-Medical Case Management): 1 unit of service = 15 minutes of direct service linkage services to an eligible PLWHA performed by a qualified service linkage worker. • Emergency Financial Assistance – Pharmacy Assistance: A unit of service = a transaction involving the filling of a prescription or any other allowable HIV treatment medication need ordered by a qualified medical practitioner. The transaction will involve at least one item being provided for the client, but can be any multiple. The cost of medications provided to the client must be invoiced at actual cost.
HRSA Service Category Definition:	• **Outpatient/Ambulatory medical care** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or

RWGA Only	nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). Primary medical care for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service's guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies. • **AIDS Pharmaceutical Assistance (local)** includes local pharmacy assistance programs implemented by Part A or Part B Grantees to provide HIV/AIDS medications to clients. This assistance can be funded with Part A grant funds and/or Part B base award funds. Local pharmacy assistance programs are not funded with ADAP earmark funding. • **Medical Case Management** services (including treatment adherence) are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case

	management including face-to-face, phone contact, and any other forms of communication. • **Case Management (non-Medical)** includes the provision of advice and assistance in obtaining medical, social, community, legal, financial, and other needed services. Non-medical case management does not involve coordination and follow-up of medical treatments, as medical case management does. • **Emergency Financial Assistance** provides limited one-time or short-term payments to assist the RWHAP client with an emergent need for paying for essential utilities, housing, food (including groceries, and food vouchers), transportation, and medication. Emergency financial assistance can occur as a direct payment to an agency or through a voucher program.
Standards of Care:	Contractors must adhere to the most current published Part A/B Standards of Care for the Houston EMA/HSDA. **Services must meet or exceed applicable United States Department of Health and Human Services (DHHS) guidelines for the Treatment of HIV/AIDS.**
Local Service Category Definition/Services to be Provided:	**Outpatient/Ambulatory Primary Medical Care:** Services include on-site physician, physician extender, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication education, and patient care coordination. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral to appropriate medical provider upon primary care Physician's order). Services provided to women shall further include OB/GYN physician & physician extender services on-site or by referral, OB/GYN services, colposcopy, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication/women's health education, patient care coordination, and social services. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral protocols to appropriate agencies upon primary care Physician's order). **Outpatient/Ambulatory Primary Medical Care must provide:** • Continuity of care for all stages of adult HIV infection;

	• Laboratory and pharmacy services including intravenous medications (either on-site or through established referral systems); • Outpatient psychiatric care, including lab work necessary for the prescribing of psychiatric medications when appropriate (either on-site or through established referral systems); • Access to the Texas ADAP program (either on-site or through established referral systems); • Access to compassionate use HIV medication programs (either directly or through established referral systems); • Access to HIV related research protocols (either directly or through established referral systems); • Must at a minimum, comply with Houston EMA/HSDA Part A/B Standards for HIV Primary Medical Care. The Contractor must demonstrate on an ongoing basis the ability to provide state-of-the-art HIV-related primary care medicine in accordance with the most recent DHHS HIV treatment guidelines. Rapid advances in HIV treatment protocols require that the Contractor provide services that to the greatest extent possible maximize a patient's opportunity for long-term survival and maintenance of the highest quality of life possible. • On-site Outpatient Psychiatry services. • On-site Medical Case Management services. • On-site Medication Education. • Physical therapy services (either on-site or via referral). • Specialty Clinic Referrals (either on-site or via referral). • On-site pelvic exams as needed for female patients with appropriate follow-up treatment and referral. • On site Nutritional Counseling by a Licensed Dietitian. **Services for women must also provide:** • Well woman care, including but not limited to: PAP, pelvic exam, HPV screening, breast examination, mammography, hormone replacement and education, pregnancy testing, contraceptive services excluding birth control medications. • Obstetric Care: ante-partum through post-partum services, child birth/delivery services. Perinatal preventative education and treatment. • On-site or by referral Colposcopy exams as needed, performed by an OB/GYN physician, or physician extender with a colposcopy provider qualification.

	• Social services, including but not limited to, providing women access to child care, transportation vouchers, food vouchers and support groups at the clinic site; **Nutritional Assessment:** Services include provision of information about therapeutic nutritional/supplemental foods that are beneficial to the wellness and increased health conditions of clients by a Licensed Dietitian. Services may be provided either through educational or counseling sessions. Clients who receive these services may utilize the Ryan White Part A-funded nutritional supplement provider to obtain recommended nutritional supplements in accordance with program rules. Clients are limited to one (1) nutritional assessment per calendar year without prior approval of RWGA. Patient Medication Education Services must adhere to the following requirements: • Medication Educators must be State Licensed Medical Doctor (MD), Nurse Practitioner (NP), Physician Assistant PA), Nurse (RN, LVN) or Pharmacist. Prior approval must be obtained prior to utilizing any other health care professional not listed above to provide medication education. • Clients who will be prescribed ongoing medical regimens (i.e. ART) must be assessed for adherence to treatment at every clinical encounter using the EMA's approved adherence assessment tool. Clients with adherence issues related to lack of understanding must receive more education regarding their medical regimen. Clients with adherence issues that are behavioral or involve mental health issues must be provided counseling by the Medical Case Manager, Physician or Physician Extender and/or licensed nursing staff and, if clinically indicated, assessment and treatment by a qualified Psychiatrist or Psychiatric Nurse Practitioner. **Outpatient Psychiatric Services:** The program must provide: • Diagnostic Assessments: comprehensive evaluation for identification of psychiatric disorders, mental status evaluation, differential diagnosis which may involve use of other clinical and laboratory tests, case formulation, and treatment plans or disposition.

	• Emergency Psychiatric Services: rapid evaluation, differential diagnosis, acute treatment, crisis intervention, and referral. Must be available on a 24 hour basis including emergency room referral. • Brief Psychotherapy: individual, supportive, group, couple, family, hypnosis, biofeedback, and other psychophysiological treatments and behavior modification. • Psychopharmacotherapy: evaluation and medication treatment of psychiatric disorders, including, but not limited to, anxiety disorders, major depression, pain syndromes, habit control problems, psychosis and organic mental disorders. • Rehabilitation Services: Physical, psychosocial, behavioral, and/or cognitive training. Screening for Eye Disorders: Contractor must ensure that patients receive appropriate screening and treatment for CMV, glaucoma, cataracts, and other related problems. **Local Medication Assistance Program (LPAP):** LPAP provides pharmaceuticals to patients otherwise ineligible for medications through private insurance, Medicaid/Medicare, State ADAP, SPAP or other sources. Allowable medications are only those on the Houston EMA Ryan White Part A Formulary. Eligible clients may be provided Fuzeon™ on a case-by-case basis with prior approval of Ryan White Grant Administration (RWGA). The cost of Fuzeon™ does not count against a client's annual maximum. HIV-related medication services are the provision of physician or physician-extender prescribed HIV-related medications to prevent serious deterioration of health. Does not include drugs available to the patient from other programs or payers or free of charge (such as birth control and TB medications) or medications available over the counter (OTC) without prescription. Contractor must offer all medications on the Texas ADAP formulary, for a total not to exceed $18,000.00 per contract year per client. Contractor must provide allowable HIV-related medications (i.e. non-HIV medications) for a total not to exceed $3,000 per contract year per client. Contractor may be reimbursed ADAP dispensing fees (e.g. $5/Rx) in accordance with RWGA business rules for those ADAP clients who are unable to pay the ADAP dispensing fee. **Medical Case Management Services:** Services include screening all primary medical care patients to determine each patient's level of need for Medical Case Management services, performing a comprehensive assessment, including an assessment of the patient's health literary, and developing a medical service plan for each client that demonstrates a documented need for such services, monitoring medical service plan to ensure its implementation, and

	educating client regarding wellness, medication and health care appointment adherence. The Medical Case Manager serves as an advocate for the client and as a liaison with medical providers on behalf of the client. The Medical Case Manager ensures linkage to mental health, substance abuse and other client services as indicated by the medical service plan. **Service Linkage:** The purpose of Service Linkage is to assist clients with the procurement of needed services so that the problems associated with living with HIV are mitigated. Service Linkage is a working agreement between a client and a Service Linkage Worker for an indeterminate period, based on client need, during which information, referrals and service linkage are provided on an as-needed basis. Service Linkage assists clients who do not require the intensity of Medical Case Management per RWGA Quality Management guidelines. Service Linkage is both office-based and field based. Service Linkage Workers are expected to coordinate activities with referral sources where newly-diagnosed or not-in-care PLWHA may be identified, including 1:1 case conferences with testing site personnel to ensure the successful transition of referrals into Primary Care Services. Such incoming referral coordination includes meeting prospective clients at the referring Provider location in order to develop rapport with individuals prior to the individual's initial Primary Care appointment and ensuring such new intakes to Primary Care services have sufficient support to make the often difficult transition into ongoing primary medical care. Service Linkage also includes follow-up to re-engage lost-to-care patients. Lost-to-care patients are those patients who have not returned for scheduled appointments with Provider nor have provided Provider with updated information about their current Primary Medical Care provider (in the situation where patient may have obtained alternate service from another medical provider). Contractor must document efforts to re-engage lost-to-care patients prior to closing patients in the CPCDMS. Service Linkage extends the capability of existing programs by providing "hands-on" outreach and linkage to care services to those PLWHA who are not currently accessing primary medical care services. Service Linkage includes the issuance of bus pass vouchers and gas cards per published RWGA guidelines. Service Linkage complements and extends the service delivery capability of Medical Case Management services. **Emergency Financial Assistance – Pharmacy Assistance** provides limited one-time and/or short-term 30-day supply of pharmaceuticals to patients otherwise ineligible for medications through private insurance, Medicaid/Medicare, State ADAP, SPAP or other sources. One refill for up to 30-day supply available with RWGA prior approval. Allowable medications are only those on the Houston EMA Ryan White Part A Formulary. HIV-related

	medication services are the provision of physician or physician-extender prescribed medications to prevent serious deterioration of health. Does not include drugs available to the patient from other programs or payers or free of charge or medications available over the counter (OTC) without prescription. Contractor must offer all medications on the Texas ADAP formulary.
Agency Requirements:	**Providers and system must be Medicaid/Medicare certified.** **Eligibility and Benefits Coordination:** Contractor must implement consumer-friendly, culturally and linguistically appropriate new and ongoing patient eligibility verification and benefit coordination processes that ensure accountability with Ryan White Payer of Last Resort requirements while achieving maximum utilization of eligible benefits. Eligibility processes should provide clients with a meaningful understanding of their benefits, expected out-of-pocket expenses and other information needed to ensure full and continued participation in care. **LPAP and EFA – Pharmacy Assistance Services:** Contractor must: Provide pharmacy services on-site or through an established contractual relationship that meets all requirements. Alternate (off-site) approaches must be approved prior to implementation by RWGA. Either directly, or via subcontract with an eligible 340B Pharmacy program entity, must: Ensure a comprehensive financial intake application to determine client eligibility for this program to insure that these funds are used as a last resort for purchase of medications. Ensure the documented capability of interfacing with the Texas HIV Medication Program operated by the Texas Department of State Health Services. This capability must be fully documented and is subject to independent verification by RWGA. Ensure medication assistance provided to clients does not duplicate services already being provided in the Houston area. The process for accomplishing this must be fully documented and is subject to independent verification by RWGA. Ensure, either directly or via a 340B Pharmacy Program Provider, at least 2 years of continuous documented experience in providing HIV/AIDS medication programs utilizing Ryan White Program or similar public sector funding. This experience must be documented and is subject to independent verification by RWGA.

	Ensure all medications are purchased via a qualified participant in the federal 340B Drug Pricing Program and Prime Vendor Program, administered by the HRSA Office of Pharmacy Affairs. Note: failure to maintain 340B or Prime Vendor drug pricing may result in a negative audit finding, cost disallowance or termination of contract awarded. Contractor must maintain 340B Program participation throughout the contract term. All eligible medications must be purchased in accordance with Program 340B guidelines and program requirements. Ensure Houston area HIV/AIDS service providers are informed of this program and how the client referral and enrollment processes functions. Contractor must maintain documentation of such marketing efforts. Implement a consistent process to enroll eligible patients in available pharmaceutical company Patient Assistance Programs prior to using Ryan White Part A funded LPAP resources. Ensure information regarding the program is provided to PLWHA, including historically under-served and unserved populations (e.g., African American, Hispanic/Latino, Asian, Native American, Pacific Islander) and women not currently obtaining prescribed HIV and HIV-related medications. Offer, at no charge to the client, delivery options for medication refills, including but not limited to courier, USPS or other package delivery service. **Case Management Operations and Supervision:** The Service Linkage Workers (SLW) and Medical Case Managers (MCM) must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds published Standards of Care. An MCM may supervise SLWs.
Staff Requirements:	Contractor is responsible for ensuring that services are provided by State licensed internal medicine and OB/GYN physicians, specialty care physicians, psychiatrists, registered nurses, nurse practitioners, vocational nurses, pharmacists, physician assistants, clinical nurse specialists, physician extenders with a colposcopy provider qualification, x-ray technologists, State licensed dieticians, licensed social worker and ancillary health care providers in accordance with appropriate State licensing and/or certification requirements and with knowledge and experience of HIV disease. In addition, Contractor must ensure the following staff requirements are met: **Outpatient Psychiatric Services:** Director of the Program must be a Board Certified Psychiatrist. Licensed and/or Certified allied health professionals (Licensed Psychologists, Physicians, Psychiatric Nurse Practitioners, Licensed Master Social Workers,

	Licensed Professional Counselors, Licensed Marriage and Family Therapists, Certified Alcohol and Drug Abuse Counselors, etc.) must be used in all treatment modalities. Documentation of the Director's credentials, licensures and certifications must be included in the proposal. Documentation of the Allied Health professional licensures and certifications must be included in the proposal appendices. **Medication and Adherence Education:** The program must utilize an RN, LVN, PA, NP, pharmacist or MD licensed by the State of Texas, who has at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care, to provide the educational services. Licensed social workers who have at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care may also provide adherence education and counseling. **Nutritional Assessment (primary care):** Services must be provided by a licensed registered dietician. Dieticians must have a minimum of two (2) years of experience providing nutritional assessment and counseling to PLWHA. **Medical Case Management:** The program must utilize a state licensed Social Worker to provide Medical Case Management Services. The Contractor must maintain the assigned number of Medical Case Management FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Medical Case Manager and the individual assigned to supervise those Medical Case Managers by 03/30/15, and thereafter within 15 days after hire.** **Service Linkage:** The program must utilize Service Linkage Workers who have at a minimum a Bachelor's degree from an accredited college or university with a major in social or behavioral sciences. Documented paid work experience in providing client services to PLWHA may be substituted for the Bachelor's degree requirement on a 1:1 basis (1 year of documented paid experience may be substituted for 1 year of college). All Service Linkage Workers must have a minimum of one (1) year paid work experience with PLWHA. Contractor must maintain the assigned number of Service Linkage FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Service Linkage Worker and the individual assigned to supervise those Service Linkage Workers by 03/30/15, and thereafter within 15 days after hire.** **Supervision of Case Managers:** The Service Linkage Workers and Medical Case Managers must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds Houston EMA/HSDA Part A/B Standards of Care

	for Service Linkage and Medical Case Management as applicable. An MCM may supervise SLWs.
Special Requirements: **RWGA Only**	**All primary medical care services must meet or exceed current United States DHHS Treatment Guidelines for the treatment and management of HIV disease.** Contractor must provide all required program components - Primary Medical Care, Medical Case Management, Service Linkage (non-medical Case Management) and Local Pharmacy Assistance Program (LPAP) services. **Primary Medical Care Services:** Services funded under this grant cannot be used to supplant insurance or Medicare/Medicaid reimbursements for such services. Clients eligible for such reimbursement may not be billed to this contract. Medicare and private insurance co-payments may be eligible for reimbursement under Ryan White Health Insurance Assistance (HINS) program guidelines. Patients needing such assistance should be referred to the local Ryan White-funded HINS provider for assistance. Under no circumstances may the Contractor bill the County for the difference between the reimbursement from Medicaid, Medicare or Third Party insurance and the fee schedule under the contract. Furthermore, potential clients who are Medicaid/Medicare eligible or have other Third Party payers may not be denied services or referred elsewhere by the Contractor based on their reimbursement status (i.e. Medicaid/Medicare eligible clients may not be referred elsewhere in order that non-Medicaid/Medicare eligible clients may be added to the contract). Failure to serve Medicaid/Medicare eligible clients based on their reimbursement status will be grounds for the immediate termination of contract. **For primary medical care services targeted to the Latino community at least 50% of the clinical care team must be fluent in Spanish.** **Diagnostic Procedures:** A single Diagnostic Procedure limited to procedures on the approved list of diagnostic procedures (see below) without prior County approval. Approved diagnostic procedures will be reimbursed at invoice cost. Part A and Part A/MAI-funded programs must refer to the RWGA website for the most current list of approved diagnostic procedures and corresponding codes: www.hcphes.org/rwga. **Diagnostic procedures not listed on the website must have prior approval by RWGA.** **Outpatient Psychiatric Services:** Client must not be eligible for services from other programs/providers or any other reimbursement source (i.e. Medicaid, Medicare, private insurance) unless the client

	is in crisis and cannot be provided immediate services from the other programs/providers. In this case, clients may be provided services, as long as the client applies for the other programs/providers, until the other programs/providers can take over services. Program must be supervised by a Psychiatrist and include diagnostic assessments, emergency evaluations and psycho-pharmacotherapy. **Maintaining Referral Relationships** (Point of Entry Agreements): Contractor must maintain appropriate relationships with entities that constitute key points of access to the health care system for individuals with HIV disease, including but not limited to, Harris Health System and other Houston EMA-located emergency rooms, Harris County Jail, Texas Department of Criminal Justice incarceration facilities, Immigration detention centers, substance abuse treatment and detoxification programs, adult and juvenile detention facilities, Sexually Transmitted Disease clinics, federally qualified health centers (FQHC), HIV disease counseling and testing sites, mental health programs and homeless shelters. These referral relationships must be documented with written collaborative agreements, contracts or memoranda of understanding between Contractor and appropriate point of entry entities and are subject to audit by RWGA. Contractor and POE entity staff must regularly (e.g. weekly, bi-weekly depending on volume of referrals) meet 1:1 to discuss new referrals to primary medical care services. Such case conferences must be documented in the client record and properly entered into the CPCDMS. Use of CPCDMS Data System: Contractor must comply with CPCDMS business rules and procedures. Contractor must enter into the CPCDMS all required clinical data, including but not limited to, HAART treatment including all changes in medication regimens, Opportunistic Infections, screening and treatment for STDs and Hepatitis A, B, C and other clinical screening and treatment data required by HRSA, TDSHS and the County. <u>Contractor must perform Registration updates in accordance with RWGA CPCDMS business rules for all clients wherein Contractor is client's CPCDMS record-owning agency. Contractor must utilize an electronic verification system to verify insurance/3rd party payer status monthly or per visit (whichever is less frequent).</u> **Bus Pass Distribution:** The County will provide Contractor with METRO bus pass vouchers. Bus Pass vouchers must be distributed in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Contractor may only issue METRO bus pass vouchers to clients wherein the Contractor is the CPCDMS record owning Contractor. METRO bus pass vouchers shall be distributed as follows:

	Expiration of Current Bus Pass: In those situation wherein the bus pass expiration date does not coincide with the CPCDMS registration update the Contractor must distribute METRO bus pass vouchers to eligible clients upon the expiration of the current bus pass or when a Value-based bus card has been expended on eligible transportation needs. Contractor may issue METRO bus passes to eligible clients living outside the METRO service area in those situations where the Contractor has documented in the client record that the client will utilize the METRO system to access needed HIV-related health care services located in the METRO service area. **Gas Cards:** Primary Medical Care Contractors must distribute gasoline vouchers to eligible clients residing in the rural service area in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Gas Cards are only available to Rural primary medical care Contractors without prior approval by RWGA.

FY 2022 RWPC "How to Best Meet the Need" Decision Process

Step in Process: **Council**		Date: **06/10/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Steering Committee**		Date: **06/03/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Quality Improvement Committee**		Date: **05/18/2021**
Recommendations:	Approved: Y:_ ___ No: _____ Approved With Changes: _____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **HTBMTN Workgroup #1**	Date: **04/20/2021**
Recommendations:	Financial Eligibility:
1.	
2.	
3.	

FY 2020 Houston EMA Ryan White Part A/MAI Service Definition **Comprehensive Outpatient Primary Medical Care including Medical Case Management and Service Linkage Services - Pediatric**	
HRSA Service Category Title: **RWGA Only**	1. Outpatient/Ambulatory Medical Care 2. Medical Case Management 3. Case Management (non-Medical)
Local Service Category Title:	Comprehensive Primary Medical Care Targeted to Pediatric
Target Population:	HIV-infected resident of the Houston EMA 0 – 18 years of age. Provider may continue services to previously enrolled clients until the client's 22nd birthday.
Financial Eligibility:	*See Current Fiscal Year Approved Financial Eligibility for Houston EMA/HSDA*
Budget Type: **RWGA Only**	Hybrid Fee for Service
Budget Requirement or Restrictions: **RWGA Only**	**Primary Medical Care:** 10% of funds designated to primary medical care must be reserved for invoicing diagnostic procedures at actual cost. Contractors may not exceed the allocation for each individual service component (Primary Medical Care, Medical Case Management and Service Linkage) without prior approval from RWGA.
Service Unit Definition/s: **RWGA Only**	• Outpatient/Ambulatory Medical Care: One (1) unit of service = One (1) primary care office/clinic visit which includes the following: • Primary care physician/nurse practitioner, physician's assistant or clinical nurse specialist examination of the patient, and • Medication/treatment education • Medication access/linkage • OB/GYN specialty procedures (as clinically indicated) • Nutritional assessment (as clinically indicated) • Laboratory (as clinically indicated, not including specialized tests) • Radiology (as clinically indicated, not including CAT scan or MRI) • Eligibility verification/screening (as necessary) • Follow-up visits wherein the patient is not seen by the MD/NP/PA are considered to be a component of the original primary care visit. • Outpatient Psychiatric Services: 1 unit of service = A single (1) office/clinic visit wherein the patient is seen by a State licensed and board-eligible Psychiatrist or qualified Psychiatric Nurse Practitioner. This visit may or may not occur on the same date as a primary care office visit. • Medical Case Management: 1 unit of service = 15 minutes of direct medical case management services to an eligible PLWHA performed by a qualified medical case manager. • Service Linkage (non-Medical Case Management): 1 unit of service = 15 minutes of direct service linkage services to an eligible

	PLWHA performed by a qualified service linkage worker.
HRSA Service Category Definition: **RWGA Only**	• **Outpatient/Ambulatory medical care** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). Primary medical care for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service's guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies. • **Medical Case Management** services (including treatment adherence) are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication. • **Case Management (non-Medical)** includes the provision of advice and assistance in obtaining medical, social, community, legal, financial, and other needed services. Non-medical case management does not involve coordination and follow-up of medical treatments, as medical case management does.
Standards of Care:	Contractors must adhere to the most current published Part A/B Standards of Care for the Houston EMA/HSDA. **Services must meet or**

	exceed applicable United States Department of Health and Human Services (DHHS) guidelines for the Treatment of HIV/AIDS.
Local Service Category Definition/Services to be Provided:	**Outpatient/Ambulatory Primary Medical Care:** Services include on-site physician, physician extender, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication education, and patient care coordination. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral to appropriate medical provider upon primary care Physician's order). Services provided to women shall further include OB/GYN physician & physician extender services on-site or by referral, OB/GYN services, colposcopy, nursing, phlebotomy, radiographic, laboratory, pharmacy, intravenous therapy, home health care referral, licensed dietician, patient medication/women's health education, patient care coordination, and social services. The Contractor must provide continuity of care with inpatient services and subspecialty services (either on-site or through specific referral protocols to appropriate agencies upon primary care Physician's order). **Outpatient/Ambulatory Primary Medical Care must provide:** • Continuity of care for all stages of adult HIV infection; • Laboratory and pharmacy services including intravenous medications (either on-site or through established referral systems); • Outpatient psychiatric care, including lab work necessary for the prescribing of psychiatric medications when appropriate (either on-site or through established referral systems); • Access to the Texas ADAP program (either on-site or through established referral systems); • Access to compassionate use HIV medication programs (either directly or through established referral systems); • Access to HIV related research protocols (either directly or through established referral systems); • Must at a minimum, comply with Houston EMA/HSDA Part A/B Standards for HIV Primary Medical Care. The Contractor must demonstrate on an ongoing basis the ability to provide state-of-the-art HIV-related primary care medicine in accordance with the most recent DHHS HIV treatment guidelines. Rapid advances in HIV treatment protocols require that the Contractor provide services that to the greatest extent possible maximize a patient's opportunity for long-term survival and maintenance of the highest quality of life possible. • On-site Outpatient Psychiatry services. • On-site Medical Case Management services. • On-site Medication Education. • Physical therapy services (either on-site or via referral).

- Specialty Clinic Referrals (either on-site or via referral).
- On-site pelvic exams as needed for female patients with appropriate follow-up treatment and referral.
- On site Nutritional Counseling by a Licensed Dietitian.

Services for females of child bearing age must also provide:

- Well woman care, including but not limited to: PAP, pelvic exam, breast examination, mammography, hormone replacement and education, pregnancy testing, contraceptive services excluding birth control medications.
- Obstetric Care: ante-partum through post-partum services, child birth/delivery services. Perinatal preventative education and treatment.
- On-site or by referral Colposcopy exams as needed, performed by an OB/GYN physician, or physician extender with a colposcopy provider qualification.
- Social services, including but not limited to, providing women access to child care, transportation vouchers, food vouchers and support groups at the clinic site;

Patient Medication Education Services must adhere to the following requirements:

- Medication Educators must be State Licensed Medical Doctor (MD), Nurse Practitioner (NP), Physician Assistant PA), Nurse (RN, LVN) or Pharmacist. Prior approval must be obtained prior to utilizing any other health care professional not listed above to provide medication education.
- Clients who will be prescribed ongoing medical regimens (i.e. ART) must be assessed for adherence to treatment at every clinical encounter using the EMA's approved adherence assessment tool. Clients with adherence issues related to lack of understanding must receive more education regarding their medical regimen. Clients with adherence issues that are behavioral or involve mental health issues must be provided counseling by the Medical Case Manager, Physician or Physician Extender and/or licensed nursing staff and, if clinically indicated, assessment and treatment by a qualified Psychiatrist or Psychiatric Nurse Practitioner.

Outpatient Psychiatric Services:

The program must provide:

- Diagnostic Assessments: comprehensive evaluation for identification of psychiatric disorders, mental status evaluation, differential diagnosis which may involve use of other clinical and laboratory tests, case formulation, and treatment plans or disposition.
- Emergency Psychiatric Services: rapid evaluation, differential diagnosis, acute treatment, crisis intervention, and referral. Must be available on a 24 hour basis including emergency room referral.

	• Brief Psychotherapy: individual, supportive, group, couple, family, hypnosis, biofeedback, and other psychophysiological treatments and behavior modification. • Psychopharmacotherapy: evaluation and medication treatment of psychiatric disorders, including, but not limited to, anxiety disorders, major depression, pain syndromes, habit control problems, psychosis and organic mental disorders. • Rehabilitation Services: Physical, psychosocial, behavioral, and/or cognitive training. Screening for Eye Disorders: Contractor must ensure that patients receive appropriate screening and treatment for CMV, glaucoma, cataracts, and other related problems. **Medical Case Management Services:** Services include screening all primary medical care patients to determine each patient's level of need for Medical Case Management services, performing a comprehensive assessment, including an assessment of the patient's health literary, and developing a medical service plan for each client that demonstrates a documented need for such services, monitoring medical service plan to ensure its implementation, and educating client regarding wellness, medication and health care appointment adherence. The Medical Case Manager serves as an advocate for the client and as a liaison with medical providers on behalf of the client. The Medical Case Manager ensures linkage to mental health, substance abuse and other client services as indicated by the medical service plan. **Service Linkage:** The purpose of Service Linkage is to assist clients with the procurement of needed services so that the problems associated with living with HIV are mitigated. Service Linkage is a working agreement between a client and a Service Linkage Worker for an indeterminate period, based on client need, during which information, referrals and service linkage are provided on an as-needed basis. Service Linkage assists clients who do not require the intensity of Medical Case Management per RWGA Quality Management guidelines. Service Linkage is both office-based and field based. Service Linkage Workers are expected to coordinate activities with referral sources where newly-diagnosed or not-in-care PLWHA may be identified, including 1:1 case conferences with testing site personnel to ensure the successful transition of referrals into Primary Care Services. Such incoming referral coordination includes meeting prospective clients at the referring Provider location in order to develop rapport with individuals prior to the individual's initial Primary Care appointment and ensuring such new intakes to Primary Care services have sufficient support to make the often difficult transition into ongoing primary medical care. Service Linkage also includes follow-up to re-engage lost-to-care patients. Lost-to-care patients are those patients who have not returned for scheduled appointments with Provider nor have provided Provider with updated information about their current Primary Medical Care provider (in the

	situation where patient may have obtained alternate service from another medical provider). Contractor must document efforts to re-engage lost-to-care patients prior to closing patients in the CPCDMS. Service Linkage extends the capability of existing programs by providing "hands-on" outreach and linkage to care services to those PLWHA who are not currently accessing primary medical care services. Service Linkage includes the issuance of bus pass vouchers and gas cards per published RWGA guidelines. Service Linkage complements and extends the service delivery capability of Medical Case Management services.
Agency Requirements:	**Providers and system must be Medicaid/Medicare certified.** **Eligibility and Benefits Coordination:** Contractor must implement consumer-friendly, culturally and linguistically appropriate new and ongoing patient eligibility verification and benefit coordination processes that ensure accountability with Ryan White Payer of Last Resort requirements while achieving maximum utilization of eligible benefits. Eligibility processes should provide clients with a meaningful understanding of their benefits, expected out-of-pocket expenses and other information needed to ensure full and continued participation in care. **Case Management Operations and Supervision:** The Service Linkage Workers (SLW) and Medical Case Managers (MCM) must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds published Standards of Care. An MCM may supervise SLWs.
Staff Requirements:	Contractor is responsible for ensuring that services are provided by State licensed internal medicine and OB/GYN physicians, specialty care physicians, psychiatrists, registered nurses, nurse practitioners, vocational nurses, pharmacists, physician assistants, clinical nurse specialists, physician extenders with a colposcopy provider qualification, x-ray technologists, State licensed dieticians, licensed social worker and ancillary health care providers in accordance with appropriate State licensing and/or certification requirements and with knowledge and experience of HIV disease. In addition, Contractor must ensure the following staff requirements are met: **Outpatient Psychiatric Services:** Director of the Program must be a Board Certified Psychiatrist. Licensed and/or Certified allied health professionals (Licensed Psychologists, Physicians, Psychiatric Nurse Practitioners, Licensed Master Social Workers, Licensed Professional Counselors, Licensed Marriage and Family Therapists, Certified Alcohol and Drug Abuse Counselors, etc.) must be used in all treatment modalities. Documentation of the Director's credentials, licensures and certifications must be included in the proposal. Documentation of the Allied Health professional licensures and certifications must be included in the proposal appendices. **Medication and Adherence Education:** The program must utilize an RN, LVN, PA, NP, pharmacist or MD licensed by the State of Texas,

	who has at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care, to provide the educational services. Licensed social workers who have at least two (2) years paid experience in the preceding five (5) years in HIV/AIDS care may also provide adherence education and counseling. **Medical Case Management:** The program must utilize a state licensed Social Worker to provide Medical Case Management Services. The Contractor must maintain the assigned number of Medical Case Management FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Medical Case Manager and the individual assigned to supervise those Medical Case Managers by 03/30/17, and thereafter within 15 days after hire.** **Service Linkage:** The program must utilize Service Linkage Workers who have at a minimum a Bachelor's degree from an accredited college or university with a major in social or behavioral sciences. Documented paid work experience in providing client services to PLWHA may be substituted for the Bachelor's degree requirement on a 1:1 basis (1 year of documented paid experience may be substituted for 1 year of college). All Service Linkage Workers must have a minimum of one (1) year paid work experience with PLWHA. Contractor must maintain the assigned number of Service Linkage FTEs throughout the contract term. **Contractor must provide to RWGA the names of each Service Linkage Worker and the individual assigned to supervise those Service Linkage Workers by 03/30/17, and thereafter within 15 days after hire.** **Supervision of Case Managers:** The Service Linkage Workers and Medical Case Managers must function within the clinical infrastructure of Contractor and receive ongoing supervision that meets or exceeds Houston EMA/HSDA Part A/B Standards of Care for Service Linkage and Medical Case Management as applicable. An MCM may supervise SLWs.
Special Requirements: **RWGA Only**	**All primary medical care services must meet or exceed current United States DHHS Treatment Guidelines for the treatment and management of HIV disease.** Contractor must provide all required program components - Primary Medical Care, Medical Case Management and Service Linkage (non-medical Case Management) services. **Primary Medical Care Services:** Services funded under this grant cannot be used to supplant insurance or Medicare/Medicaid reimbursements for such services. Clients eligible for such reimbursement may not be billed to this contract. Medicare and private insurance co-payments may be eligible for reimbursement under Ryan White Health Insurance Assistance (HINS) program guidelines. Patients needing such assistance should be referred to the local Ryan White-funded HINS provider for assistance. Under no circumstances may the

	Contractor bill the County for the difference between the reimbursement from Medicaid, Medicare or Third Party insurance and the fee schedule under the contract. Furthermore, potential clients who are Medicaid/Medicare eligible or have other Third Party payers may not be denied services or referred elsewhere by the Contractor based on their reimbursement status (i.e. Medicaid/Medicare eligible clients may not be referred elsewhere in order that non-Medicaid/Medicare eligible clients may be added to the contract). Failure to serve Medicaid/Medicare eligible clients based on their reimbursement status will be grounds for the immediate termination of contract. **Diagnostic Procedures:** A single Diagnostic Procedure limited to procedures on the approved list of diagnostic procedures (see below) without prior County approval. Approved diagnostic procedures will be reimbursed at invoice cost. Part A and Part A/MAI-funded programs must refer to the RWGA website for the most current list of approved diagnostic procedures and corresponding codes: www.hcphes.org/rwga. **Diagnostic procedures not listed on the website must have prior approval by RWGA.** **Outpatient Psychiatric Services:** Client must not be eligible for services from other programs/providers or any other reimbursement source (i.e. Medicaid, Medicare, private insurance) unless the client is in crisis and cannot be provided immediate services from the other programs/providers. In this case, clients may be provided services, as long as the client applies for the other programs/providers, until the other programs/providers can take over services. Program must be supervised by a Psychiatrist and include diagnostic assessments, emergency evaluations and psycho-pharmacotherapy. **Maintaining Referral Relationships** (Point of Entry Agreements): Contractor must maintain appropriate relationships with entities that constitute key points of access to the health care system for individuals with HIV disease, including but not limited to, Harris Health System and other Houston EMA-located emergency rooms, Harris County Jail, Texas Department of Criminal Justice incarceration facilities, Immigration detention centers, substance abuse treatment and detoxification programs, adult and juvenile detention facilities, Sexually Transmitted Disease clinics, federally qualified health centers (FQHC), HIV disease counseling and testing sites, mental health programs and homeless shelters. These referral relationships must be documented with written collaborative agreements, contracts or memoranda of understanding between Contractor and appropriate point of entry entities and are subject to audit by RWGA. Contractor and POE entity staff must regularly (e.g. weekly, bi-weekly depending on volume of referrals) meet 1:1 to discuss new referrals to primary medical care services. Such case conferences must be documented in the client record and properly entered into the CPCDMS. Use of CPCDMS Data System: Contractor must comply with CPCDMS

	business rules and procedures. Contractor must enter into the CPCDMS all required clinical data, including but not limited to, HAART treatment including all changes in medication regimens, Opportunistic Infections, screening and treatment for STDs and Hepatitis A, B, C and other clinical screening and treatment data required by HRSA, TDSHS and the County. Contractor must perform Registration updates in accordance with RWGA CPCDMS business rules for all clients wherein Contractor is client's CPCDMS record-owning agency. Contractor must utilize an electronic verification system to verify insurance/3rd party payer status monthly or per visit (whichever is less frequent). **Bus Pass Distribution:** The County will provide Contractor with METRO bus pass vouchers. Bus Pass vouchers must be distributed in accordance with RWGA policies and procedures, standards of care and financial eligibility guidelines. Contractor may only issue METRO bus pass vouchers to clients wherein the Contractor is the CPCDMS record owning Contractor. METRO bus pass vouchers shall be distributed as follows: **Expiration of Current Bus Pass:** In those situation wherein the bus pass expiration date does not coincide with the CPCDMS registration update the Contractor must distribute METRO bus pass vouchers to eligible clients upon the expiration of the current bus pass or when a Value-based bus card has been expended on eligible transportation needs. Contractor may issue METRO bus passes to eligible clients living outside the METRO service area in those situations where the Contractor has documented in the client record that the client will utilize the METRO system to access needed HIV-related health care services located in the METRO service area.

FY 2022 RWPC "How to Best Meet the Need" Decision Process

Step in Process: **Council**		Date: **06/10/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Steering Committee**		Date: **06/03/2021**
Recommendations:	Approved: Y:_____ No: _____ Approved With Changes:_____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **Quality Improvement Committee**		Date: **05/18/2021**
Recommendations:	Approved: Y:_ ___ No: _____ Approved With Changes: _____	If approved with changes list changes below:
1.		
2.		
3.		

Step in Process: **HTBMTN Workgroup #1**	Date: **04/20/2021**
Recommendations:	Financial Eligibility:
1.	
2.	
3.	

Umair A. Shah, M.D., M.P.H.
Executive Director
2223 West Loop South
Houston, Texas 77027
Tel: (713) 439-6000
Fax: (713) 439-6080

Harris County Public Health
Building a Healthy Community

Michael Ha
Disease Control & Clinical Prevention Division
2223 West Loop South
Houston, Texas 77027
Tel: (713) 439-6000
Fax: (713) 439-6199

FY 2019 PERFORMANCE MEASURES HIGHLIGHTS
RYAN WHITE GRANT ADMINISTRATION
HARRIS COUNTY PUBLIC HEALTH (HCPH)

TABLE OF CONTENTS

HCPH is the local public health agency for the Harris County, Texas jurisdiction. It provides a wide variety of public health activities and services aimed at improving the health and well-being of the Harris County community.

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Highlights from FY 2019 Performance Measures

Measures in this report are based on the 2019/2020 Houston Ryan White Quality Management Plan, Appendix B. HIV Performance Measures.

Medical Case Management

- During FY 2019, 5,304 clients utilized Part A medical case management. According to CPCDMS, 2,644 (50%) of these clients accessed primary care two or more times at least three months apart during this time period after utilizing medical case management.
- Among these clients, 13% of clients accessed mental health services at least once during this time period after utilizing medical case management.
- For clients who have lab data in CPCDMS, 73% were virally suppressed.

Outreach

- During FY 2019, 215 (34%) clients accessed primary care within three months of their first outreach visit.
- 66% of FY 2018 clients moved from an unsuppressed to suppressed viral load status within six to twelve months after their first outreach visit.

Primary Medical Care

- During FY 2019, 8,620 clients utilized Part A primary medical care. According to CPCDMS, 5,040 (75%) of these clients accessed primary care two or more times at least three months apart during this time period.
- Among clients whose initial primary care medical visit occurred during this time period, 18% had a CD4 < 200 within the first 90 days of initial enrollment in primary medical care.
- Among these clients, 86% had a viral load test performed at least every six months during this time period. Among clients with viral load tests, 78% were virally suppressed during this time period.
- 69% of new clients were engaged in care during this time period.
- During FY 2019, the average wait time for an initial appointment availability to enroll in primary medical care was 10 days, while the average wait time for an appointment availability to receive primary medical care was 8 days.

Service Linkage (Non-Medical Case Management)

- During FY 2019, 8,717 clients utilized Part A non-medical case management / service linkage. According to CPCDMS, 4,174 (48%) of these clients accessed primary care two or more times at least three months apart during this time period after utilizing non-medical case management.
- Among these clients, 50% of clients utilized primary medical care for the first time after accessing service linkage for the first time.
- The median number of days between the first service linkage visit and the first primary medical care visit was 14 days during this time period.

Vision Care

- During FY 2019, 871 clients were diagnosed with HIV/AIDS related and general ocular disorders. Among 130 clients with follow-up appointments, 6% of clients had disorders that were either resolved or improved, while 90% of clients had disorders that remained the same.

Ryan White Part A
HIV Performance Measures
FY 2019 Report

Local Pharmacy Assistance
All Providers

HIV Performance Measures	FY 2018	FY 2019	Change
75% of clients for whom there is lab data in the CPCDMS will be virally suppressed (<200)	3,118 (77.9%)	3,537 (79.1%)	**1.2%**

Ryan White Part A
HIV Performance Measures
FY 2019 Report

Medical Case Management
All Providers

For FY 2019 (3/1/2019 to 2/29/2020), 5,304 clients utilized Part A medical case management.

HIV Performance Measures	FY 2018	FY 2019	Change
A minimum of 85% of clients will utilize Part A/B/C/D primary care two or more times at least three months apart after accessing medical case management	3,177 (52.2%)	2,644 (49.9%)	**-2.3%**
15% of medical case management clients will utilize mental health services	799 (13.1%)	680 (12.8%)	**-0.3%**
45% of clients who have third-party payer coverage (e.g. Medicare, Medicaid, private insurance) after accessing medical case management	*N/A	1,580 (29.8%)	**N/A**
75% of clients for whom there is lab data in the CPCDMS will be virally suppressed (<200)	2,489 (74.0%)	1,996 (72.7%)	**-1.3%**
50% of clients will have at least one medical visit in each six-month period of the 24-month measurement period with a minimum of 60 days between medical visits	1,118 (38.2%)		
Less than 20% of clients will have more than a six month gap in medical care in the measurement year	753 (24.3%)	605 (23.4%)	**-0.9%**
Less than 15% of clients will be homeless or unstably housed	1,022 (16.8%)	760 (14.3%)	**-2.5%**

According to CPCDMS, 125 (2.4%) clients utilized primary care for the first time and 184 (3.5%) clients utilized mental health services for the first time after accessing medical case management.

*Note that the methodology of how this data is analyzed is being refined. Due to the way insurance data is collected, FY18 data cannot be re-evaluated.

Clinical Chart Review Measures	FY 2018
60% of medical case management clients will have a case management care plan developed and/or updated two or more times in the measurement year	11%

Ryan White Part A
HIV Performance Measures
FY 2019 Report

Outreach Services
All Providers

HIV Performance Measures	FY 2018	FY 2019	Change
Percentage of clients who attended a primary care visit within three months of the first Outreach visit	311 (39.1%)	215 (34.4%)	**-4.7%**
Percentage of clients who attended a primary are visit within three months of the first Outreach visit and a subsequent visit 6 to 12 months thereafter	206 (66.2%)	*N/A	**N/A**
Percentage of clients who went from an unsuppressed VL (>=200 copies/ml) to a suppressed viral load (<200 copies/ml) within 12 months of the first Outreach visit	268 (54.9%)	*N/A	**N/A**

*Please note that due to the time parameters for this measure, data can only be produced for the previous fiscal year.

Ryan White Part A
HIV Performance Measures
FY 2019 Report

Primary Medical Care
All Providers

For FY 2019 (3/1/2019 to 2/29/2020), 8,620 clients utilized Part A primary medical care.

HIV Performance Measures	FY 2018	FY 2019	Change
90% of clients will have two or more medical visits, at least 90 days apart, in an HIV care setting in the measurement year	4,624 (74.5%)	5,040 (75.3%)	**0.8%**
Less than 20% of clients will have a CD4 < 200 within the first 90 days of initial enrollment in primary medical care	304 (19.8%)	273 (17.7%)	**-2.1%**
95% of clients will have Hepatitis C (HCV) screening performed at least once since HIV diagnosis	5,967 (74.0%)	6,050 (70.2%)	**-3.8%**
30% of clients will receive an oral exam by a dentist at least once during the measurement year	2,034 (25.2%)	2,179 (25.3%)	**0.1%**
85% of clients will have a test for syphilis performed within the measurement year	6,648 (82.5%)	7,127 (82.7%)	**0.2%**
95% of clients will be screened for Hepatitis B virus infection status at least once since HIV diagnosis	6,726 (83.5%)	7,337 (85.1%)	**1.6%**
90% of clients will have a viral load test performed at least every six months during the measurement year	4,063 (82.1%)	4,647 (86.3%)	**4.2%**
90% of clients for whom there is lab data in the CPCDMS will be virally suppressed (<200)	6,139 (76.2%)	6,742 (78.2%)	**2.0%**
35% of clients will have at least one medical visit in each six-month period of the 24-month measurement period with a minimum of 60 days between medical visits	2,677 (25.0%)		
Less than 20% of clients will have more than a six month gap in medical care in the measurement year	1,719 (27.7%)	1,855 (27.7%)	**0.0%**
60% of new clients will be engaged in care	420 (70.5%)	383 (68.5%)	**-2.0%**
100% of Ryan White Part A program-funded outpatient/ambulatory care organizations in the system/network will have a wait time of 15 or fewer business days for a Ryan White Part A program-eligible patient to receive an initial appointment to enroll in outpatient/ambulatory medical care	**Data below**		
100% of Ryan White Part A program-funded outpatient/ambulatory care organizations in the system/network will have a wait time of 15 or fewer business days for a Ryan White Part A program-eligible patient to receive an appointment for outpatient/ambulatory medical care	**Data below**		

For FY 2019, 83% of Ryan White Part A outpatient/ambulatory care organizations provided a waiting time of 15 or fewer business days for a program-eligible patient to receive an initial appointment to enroll in medical care.

Average wait time for initial appointment availability to enroll in outpatient/ambulatory medical care: EMA = 10 Days

Agency 1:	9
Agency 2:	5
Agency 3:	17
Agency 4:	12
Agency 5:	9
Agency 6:	10

For FY 2019, 100% of Ryan White Part A outpatient/ambulatory care organizations provided a waiting time of 15 or fewer business days for a program-eligible patient to receive an appointment for medical care.

Average wait time for appointment availability to receive outpatient/ambulatory medical care: EMA = 8 Days

Agency 1:	11
Agency 2:	4
Agency 3:	14
Agency 4:	5
Agency 5:	5
Agency 6:	8

Clinical Chart Review Measures*	FY 2017	FY 2018
100% of eligible clients will be prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis	93.0%	93.9%
100% of pregnant women living with HIV will be prescribed antiretroviral therapy	100%	100%
75% of female clients will have received cervical cancer screening in the past three years	82.5%	81.6%
55% of clients will complete the vaccination series for Hepatitis B	51.4%	49.3%
85% of clients will receive HIV risk counseling within the measurement year	90.7%	83.9%
95% of clients will be screened for substance abuse (alcohol and drugs) in the measurement year	99.1%	99.4%
90% of clients who were prescribed antiretroviral therapy will have a fasting lipid panel during the measurement year	88.8%	89.9%
65% of clients at risk for sexually transmitted infections will have a test for gonorrhea and chlamydia within the measurement year	77.6%	78.9%
75% of clients will have documentation that a TB screening test was performed and results interpreted (for tuberculin skin tests) at least once since HIV diagnosis	67.2%	71.0%
65% of clients seen for a visit between October 1 and March 31 will receive an influenza immunization OR will report previous receipt of an influenza immunization	53.5%	62.9%
95% of clients will be screened for clinical depression using a standardized tool with follow-up plan documented	96.4%	98.1%
90% of clients will have ever received pneumococcal vaccine	83.4%	83.1%
100% of clients will be screened for tobacco use at least one during the two-year measurement period	100%	98.7%
Percentage of clients who received cessation counseling intervention if identified as a tobacco user	55.7%	67.8%
95% of clients will be prescribed antiretroviral therapy during the measurement year	98.7%	99.4%
85% of clients will have an HIV drug resistance test performed before initiation of HIV antiretroviral therapy if therapy started during the measurement year	71.4%	75.0%
75% of eligible reproductive-age women will receive reproductive health care (fertility desires assessed and client counseled on conception or contraception)	34.9%	53.7%
90% of clients will be screened for Intimate Partner Violence	78.6%	93.2%
100% of clients on ART will be screened for adherence	100.0%	100%

* To view the full FY 2018 chart review reports, please visit:
http://publichealth.harriscountytx.gov/Services-Programs/Programs/RyanWhite/Quality

Ryan White Part A
HIV Performance Measures
FY 2019 Report

Service Linkage / Non-Medical Case Management
All Providers

For FY 2019 (3/1/2019 to 2/29/2020), 8,717 clients utilized Part A non-medical case management.

HIV Performance Measures	FY 2018	FY 2019	Change
A minimum of 70% of clients will utilize Part A/B/C/D primary care two or more times at least three months apart after accessing non-medical case management (service linkage)	3,548 (46.4%)	4,174 (47.9%)	**1.5%**
60% of clients will access RW primary medical care for the first time after accessing service linkage for the first time	459 (48.9%)	501 (49.6%)	**0.7%**
Mean of less than 30 days between first ever service linkage visit and first ever primary medical care visit:			
Mean	32	28	**-12.5%**
Median	15	14	**-6.7%**
Mode	1	1	**0.0%**
60% of newly enrolled clients will have a medical visit in each of the four-month periods of the measurement year	133 (47.7%)	128 (45.2%)	**-2.5%**

Umair A. Shah, M.D., M.P.H.
Executive Director

Harris County Public Health
Building a Healthy Community

2223 West Loop South
Houston, Texas 77027
Tel: (713) 439-6000
Fax: (713) 439-6080

Primary Care Chart Review Report FY 2019

Ryan White Part A Quality Management Program – Houston EMA

November 2020

CONTACT:

Heather Keizman, RN, MSN, WHNP-BC
Project Coordinator-Clinical Quality Improvement
Harris County Public Health
Ryan White Grant Administration Section
2223 West Loop South
Houston, TX 77027
832-927-7629

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PREFACE

EXPLANATION OF PART A QUALITY MANAGEMENT

In 2019, the Houston Eligible Metropolitan Area (EMA) awarded Part A funds for adult Outpatient Ambulatory Medical Services to five organizations. Approximately 13,000 unduplicated individuals living with HIV receive Ryan White-funded services at these organizations.

Harris County Public Health (HCPH) must ensure the quality and cost effectiveness of primary medical care. The medical services chart review is performed to ensure that the medical care provided adheres to current evidence-based guidelines and standards of care. The Ryan White Grant Administration (RWGA) Project Coordinator for Clinical Quality Improvement (PC/CQI) performed the medical services review.

Introduction

On March 30, 2019, the RWGA PC/CQI commenced the evaluation of Part A funded Primary Medical Care Services funded by the Ryan White Part A grant. This grant is awarded to HCPH by the Health Resources and Services Administration (HRSA) to provide HIV-related health and social services to people living with HIV. The purpose of this evaluation project is to meet HRSA mandates for quality management, with a focus on:

- evaluating the extent to which primary care services adhere to the most current United States Department of Health and Human Services (DHHS) HIV treatment guidelines;
- provide statistically significant primary care utilization data including demographics of individuals receiving care; and,
- make recommendations for improvement.

A comprehensive review of client medical records was conducted for services provided between 3/1/19 and 2/29/20. The guidelines in effect during the year the patient sample was seen, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* were used to determine degree of compliance. The current treatment guidelines are available for download at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. The initial activity to fulfill the purpose was the development of a medical record data abstraction tool that addresses elements of the guidelines, followed by medical record review, data analysis and reporting of findings with recommendations.

Tool Development

The PC/CQI worked with the Clinical Quality Improvement (CQI) committee to develop and approve data collection elements and processes that would allow evaluation of primary care services based on the most current *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* that were developed by the Panel on Antiretroviral Guidelines for Adults and Adolescents convened by the DHHS. In addition, data collection elements and processes were developed to align with the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau's (HAB) HIV/AIDS Clinical Performance Measures for Adults & Adolescents. These measures are designed to serve as indicators of quality care. HAB measures are available for download at: http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html. An electronic database was designed to facilitate direct data entry from patient records. Automatic edits and validation screens were included in the design and layout of the data abstraction program to "walk" the nurse reviewer through the process and to facilitate the accurate collection, entering and validation of data. Inconsistent information, such as reporting GYN exams for men, or opportunistic infection prophylaxis for patients who do not need it, was considered when designing validation functions. The PC/CQI then used detailed data validation reports to check certain values for each patient to ensure they were consistent.

Chart Review Process

All charts were reviewed by a Master's-level registered nurse experienced in identifying documentation issues and assessing adherence to treatment guidelines. The collected data for each site was recorded directly into a preformatted computerized database. The data collected during this process is to be used for service improvement.

If documentation on a particular element was not found, a "no data" response was entered into the database. For some data elements, the reviewer looked for documentation that the requisite test/assessment/vaccination was performed, e.g., lipid screening or pneumococcal vaccination. Other data elements required that several questions be answered in an "if, then" format. For example, if a Pap smear was abnormal, then was a colposcopy performed? This logic tree type of question allows more in-depth assessment of care and a greater ability to describe the level of quality. Using another example, if only one question is asked, such as "was a mental health screening done?" the only assessment that can be reported is how many patients were screened. More questions need to be asked to evaluate quality and the appropriate assessment and treatment, e.g., if the mental health screening was positive, was the client referred? If the client accepted a referral, were they able to access a Mental Health Provider?

The specific parameters established for the data collection process were developed from national HIV care guidelines.

Tale 1. Data Collection Parameters

Review Item	Standard
Primary Care Visits	Primary care visits during review period, denoting date and provider type (MD, NP, PA, other). There is no standard of care to be met per se. Data for this item is strictly for analysis purposes only
Annual Exams	Dental exams are recommended annually
Mental Health	A Mental Health screening is recommended annually screening for depression, anxiety, and associated psychiatric issues
Substance Abuse	Clients should be screened for substance abuse potential annually and referred accordingly

Tale 1. Data Collection Parameters (cont.)	
Review Item	Standard
Antiretroviral Therapy (ART) adherence	Adherence to medications should be documented at every visit with issues addressed as they arise
Lab	Viral Load Assays are recommended every 3-6 months. Clients on ART should have a Lipid Profile annually (minimum recommendations)
STD Screen	Screening for Syphilis, Gonorrhea, and Chlamydia should be performed at least annually for clients at risk
Hepatitis Screen	Screening for Hepatitis B and C are recommended at initiation to care. At risk clients not previously immunized for Hepatitis A and B should be offered vaccination.
Tuberculosis Screen	Screening is recommended at least once since HIV diagnosis, either PPD, IGRA or chest X-ray.
Cervical Cancer Screen	Women are assessed for at least one PAP smear during the previous three years
Immunizations	Clients are assessed for annual Flu immunizations and whether they have ever received pneumococcal vaccination.
HIV Risk Counseling	Clients are screened for behaviors associated with HIV transmission and risk reduction discussed
Pneumocystis jirovecii Pneumonia (PCP) Prophylaxis	Labs are reviewed to determine if the client meets established criteria for prophylaxis

The Sample Selection Process

The sample population was selected from a pool of 8,174 clients (adults age 18+) who accessed Part A primary care (excluding vision care) and had at least two visits, at least 90 days apart, between 3/1/19 and 2/29/20. The medical charts of 635 clients were used in this review, representing 7.8% of the pool of unduplicated clients. The number of clients selected at each site is proportional to the number of primary care clients served there. Three caveats were observed during the sampling process. In an effort to focus on women living with HIV health issues, women were over-sampled, comprising 42.7% of the sample population. Second, providers serving a relatively small number of clients were over-sampled in order to ensure sufficient sample sizes for data analysis. Finally, transgender clients were oversampled in order to collect data on this sub-population.

In an effort to make the sample population as representative of the Part A primary care population as possible, the EMA's Centralized Patient Care Data Management System (CPCDMS) was used to generate the lists of client codes for each site. The demographic

make-up (race/ethnicity, gender, age) of clients who accessed primary care services at a particular site during the study period was determined by CPCDMS. A sample was then generated to closely mirror that same demographic make-up.

Characteristics of the Sample Population

Due to the desire to over sample for female clients, the review sample population is not generally comparable to the Part A population receiving outpatient primary medical care in terms of race/ethnicity, gender, and age. No medical records of children/adolescents were reviewed, as clinical guidelines for these groups differ from those of adult patients. Table 2 compares the review sample population with the Ryan White Part A primary care population as a whole.

Table 2. Demographic Characteristics of Clients During Study Period 3/1/19-2/28/20

	Sample		**Ryan White Part A Houston EMA**	
Gender	Number	Percent	Number	Percent
Male	334	52.6%	6,046	74%
Female	271	42.7%	1,976	24.2%
Transgender Male to Female	30	4.7%	151	1.9%
Transgender Female to Male	0	0%	1	.01%
TOTAL	**635**		**8,174**	
Race				
Asian	9	1.4%	111	1.4%
African-Amer.	302	47.6%	4,002	49%
Pacific Islander	0	0%	7	.1%
Multi-Race	2	.3%	65	.8%
Native Amer.	2	.3%	28	.3%
White	320	50.4%	3,961	48.5%
TOTAL	**635**		**8,174**	
Hispanic				
Non-Hispanic	388	61.1%	5,105	62.5%
Hispanic	247	38.9%	3,069	37.6%
TOTAL	**635**		**8,174**	
Age				
<=24	24	3.8%	420	5.1%
25-34	177	27.9%	2,385	29.2%
35-44	160	25.2%	2,290	28%
45-49	82	12.9%	981	12%
50-64	184	29%	1,982	24.2%
65 and older	8	1.3%	116	1.4%
Total	**635**		**8,174**	

Report Structure

In November 2013, the Health Resource and Services Administration's (HRSA), HIV/AIDS Bureau (HAB) revised its performance measure portfolio[1]. The categories included in this report are: Core, All Ages, and Adolescents/Adult. These measures are intended to serve as indicators for use in monitoring the quality of care provided to patients receiving Ryan White funded clinical care. In addition to the HAB measures, several other primary care performance measures are included in this report. When available, data and results from the two preceding years are provided, as well as comparison to EMA goals. Performance measures are also depicted with results categorized by race/ethnicity.

[1] http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html

Findings

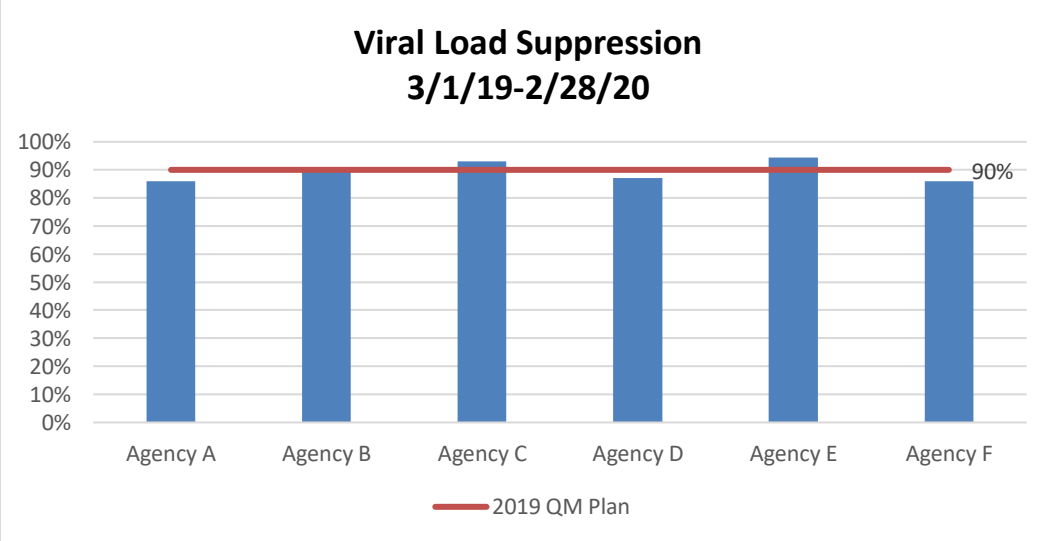
Core Performance Measures

Viral Load Suppression

- Percentage of clients living with HIV with viral load below limits of quantification (defined as <200 copies/ml) at last test during the measurement year

	2017	2018	2019
Number of clients with viral load below limits of quantification at last test during the measurement year	535	553	559
Number of clients who: • had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year, and • were prescribed ART for at least 6 months	626	630	625
Rate	**85.5%**	**87.8%**	**89.4%**
	-3%	**2.3%**	**1.6%**

2019 Viral Load Suppression by Race/Ethnicity			
	Black	Hispanic	White
Number of clients with viral load below limits of quantification at last test during the measurement year	230	227	92
Number of clients who: • had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year, and • were prescribed ART for at least 6 months	266	246	102
Rate	**86.5%**	**92.3%**	**90.2%**



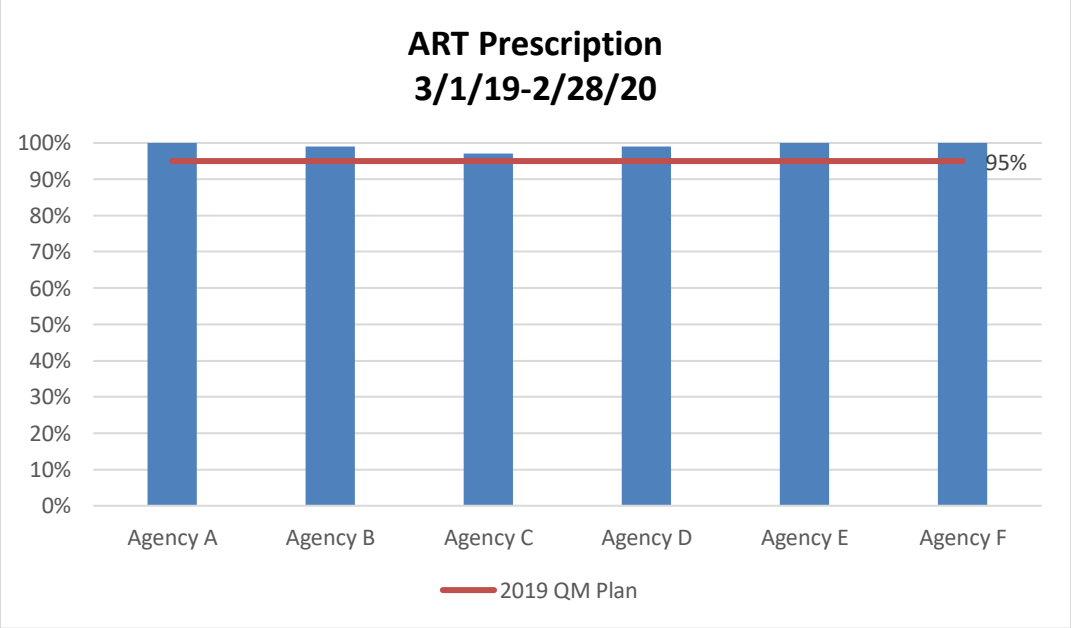
ART Prescription

- Percentage of clients living with HIV who are prescribed antiretroviral therapy (ART)

	2017	2018	2019
Number of clients who were prescribed an ART regimen within the measurement year	627	631	627
Number of clients who: • had at least two medical visit with a provider with prescribing privileges, i.e. MD, PA, NP in the measurement year	635	635	635
Rate	**98.7%**	**99.4%**	**98.7%**
Change from Previous Years Results	**1.1%**	**.7%**	**-.7%**

- Of the 8 clients not on ART, none had a CD4 <200, 5 were elite controllers/long-term non-progressors, and 3 refused

2019 ART Prescription by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who were prescribed an ART regimen within the measurement year	267	247	102
Number of clients who: • had at least two medical visit with a provider with prescribing privileges, i.e. MD, PA, NP in the measurement year	272	247	105
Rate	**98.2%**	**100%**	**97.1%**

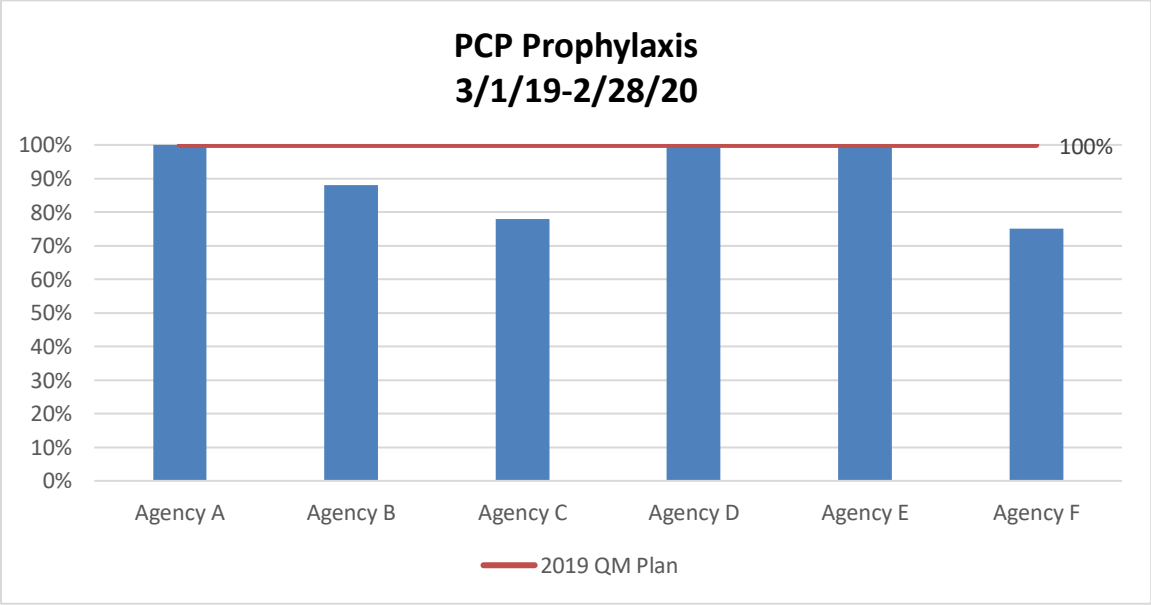


PCP Prophylaxis

- Percentage of clients living with HIV and a CD4 T-cell count below 200 cells/mm^3 who were prescribed PCP prophylaxis

	2017	2018	2019
Number of clients with CD4 T-cell counts below 200 cells/mm^3 who were prescribed PCP prophylaxis	53	62	34
Number of clients who: • had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year, and • had a CD4 T-cell count below 200 cells/mm^3, or any other indicating condition	57	66	38
Rate	**93%**	**93.9%**	**89.5%**
Change from Previous Years Results	**-7%**	**.9%**	**-4.4%**

2019 PCP Prophylaxis by Race/Ethnicity			
	Black	Hispanic	White
Number of clients with CD4 T-cell counts below 200 cells/mm^3 who were prescribed PCP prophylaxis	11	14	6
Number of clients who: • had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least once in the measurement year, and • had a CD4 T-cell count below 200 cells/mm^3, or any other indicating condition	12	17	6
Rate	**91.7%**	**82.4%**	**100%**



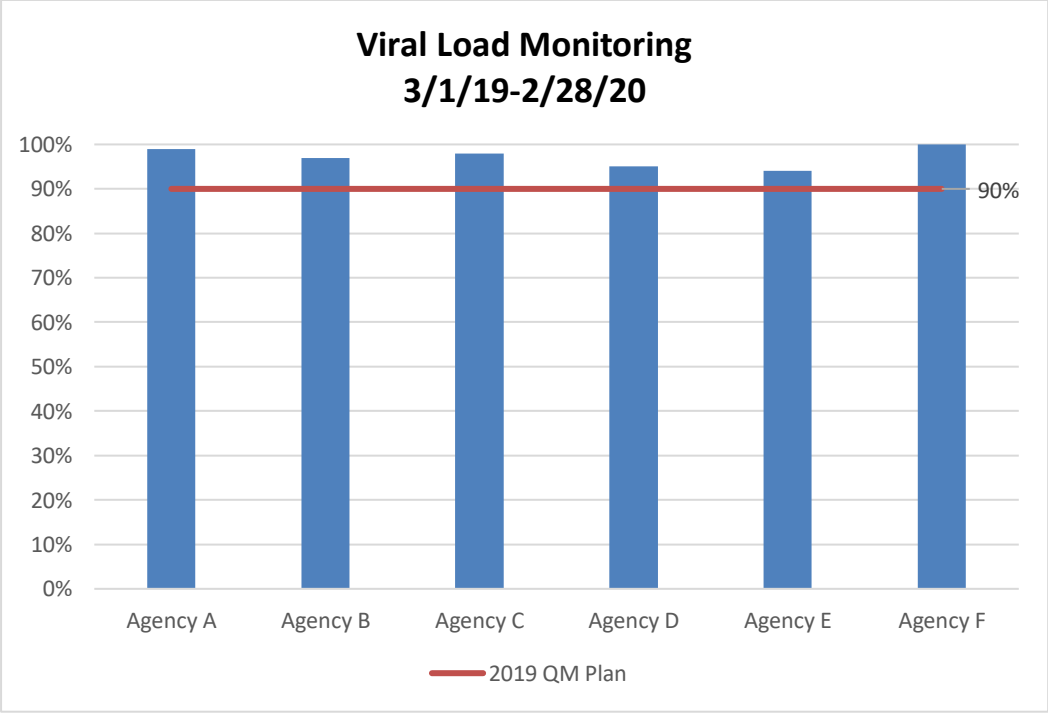
All Ages Performance Measures

Viral Load Monitoring

- Percentage of clients living with HIV who had a viral load test performed at least every six months during the measurement year

	2017	2018	2019
Number of clients who had a viral load test performed at least every six months during the measurement year	622	624	619
Number of clients who had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year	635	635	635
Rate	**98%**	**98.3%**	**97.5%**
Change from Previous Years Results	**3.4%**	**.3%**	**-.8%**

2019 Viral Load by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who had a viral load test performed at least every six months during the measurement year	262	246	100
Number of clients who had a medical visit with a provider with prescribing privileges1, i.e. MD, PA, NP at least twice in the measurement year	272	247	105
Rate	**96.3%**	**99.6%**	**95.2%**



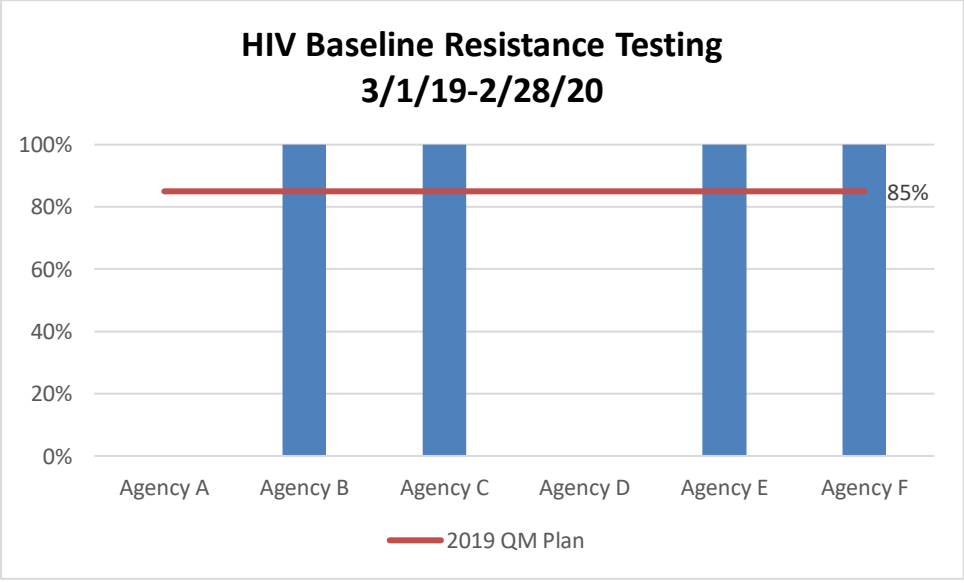
HIV Drug Resistance Testing Before Initiation of Therapy

- Percentage of clients living with HIV who had an HIV drug resistance test performed before initiation of HIV ART if therapy started in the measurement year

	2017	2018	2019
Number of clients who had an HIV drug resistance test performed at any time before initiation of HIV ART	5	6	5
Number of clients who: • had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year, and • were prescribed ART during the measurement year for the first time	7	8	7
Rate	**71.4%**	**75%**	**71.4%**
Change from Previous Years Results	**2.2%**	**3.6%**	**-3.6%**

2019 Drug Resistance Testing by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who had an HIV drug resistance test performed at any time before initiation of HIV ART	1	3	1
Number of clients who: • had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year, and • were prescribed ART during the measurement year for the first time	2	4	1
Rate	**50%**	**75%**	**100%**

*Agency A did not have any clients that met the denominator



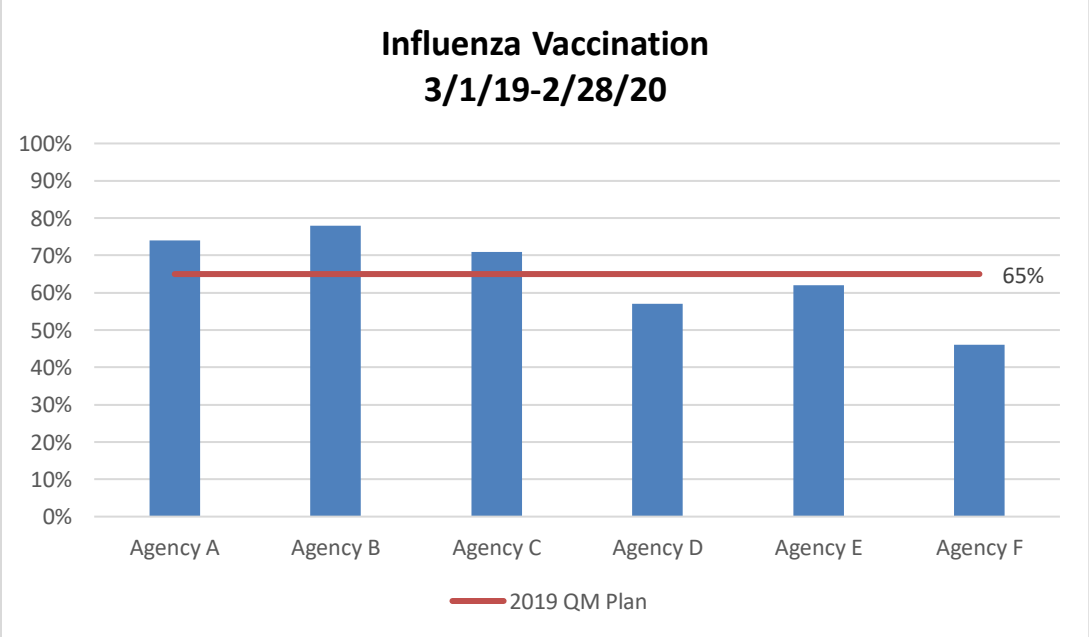
Influenza Vaccination

- Percentage of clients living with HIV who have received influenza vaccination within the measurement year

	2017	2018	2019
Number of clients who received influenza vaccination within the measurement year	310	336	362
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement period	579	534	531
Rate	**53.5%**	**62.9%**	**68.2%**
Change from Previous Years Results	**.4%**	**9.4%**	**5.3%**

- The definition excludes from the denominator medical, patient, or system reasons for not receiving influenza vaccination

2019 Influenza Screening by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who received influenza vaccination within the measurement year	124	168	62
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	212	215	93
Rate	**58.5%**	**78.1%**	**66.7%**

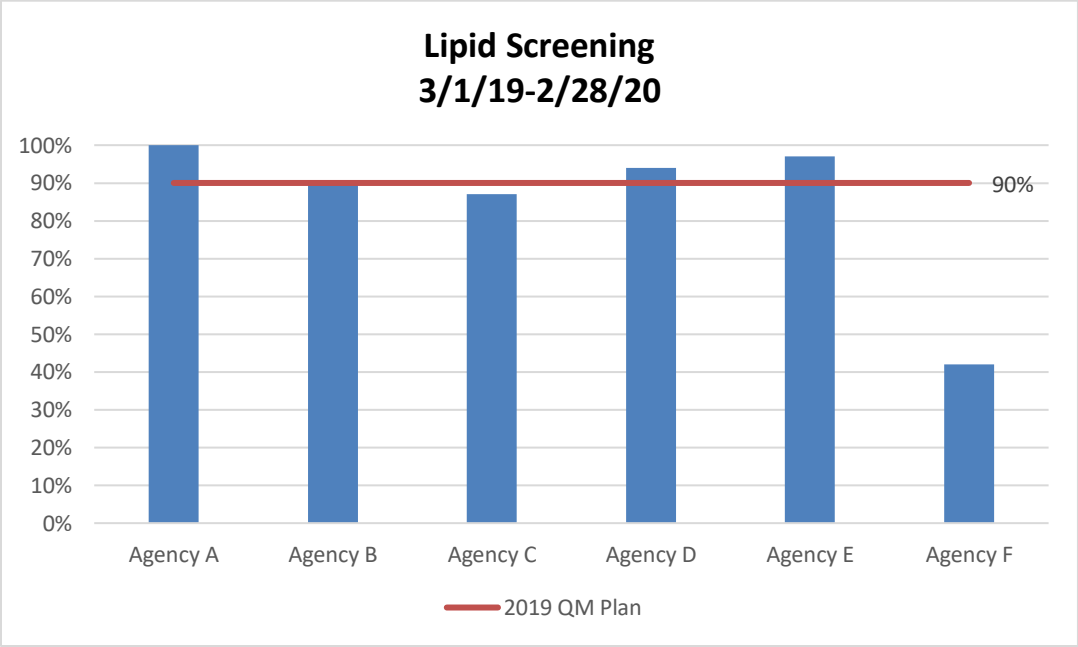


Lipid Screening

- Percentage of clients living with HIV on ART who had fasting lipid panel during measurement year

	2017	2018	2019
Number of clients who: • were prescribed ART, and • had a fasting lipid panel in the measurement year	557	567	554
Number of clients who are on ART and who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	627	631	627
Rate	**88.8%**	**89.9%**	**88.4%**
Change from Previous Years Results	**-.1%**	**1.1%**	**-1.5%**

2019 Lipid Screening by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who: • were prescribed ART, and • had a fasting lipid panel in the measurement year	236	216	91
Number of clients who are on ART and who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	267	247	102
Rate	**88.4%**	**87.4%**	**89.2%**

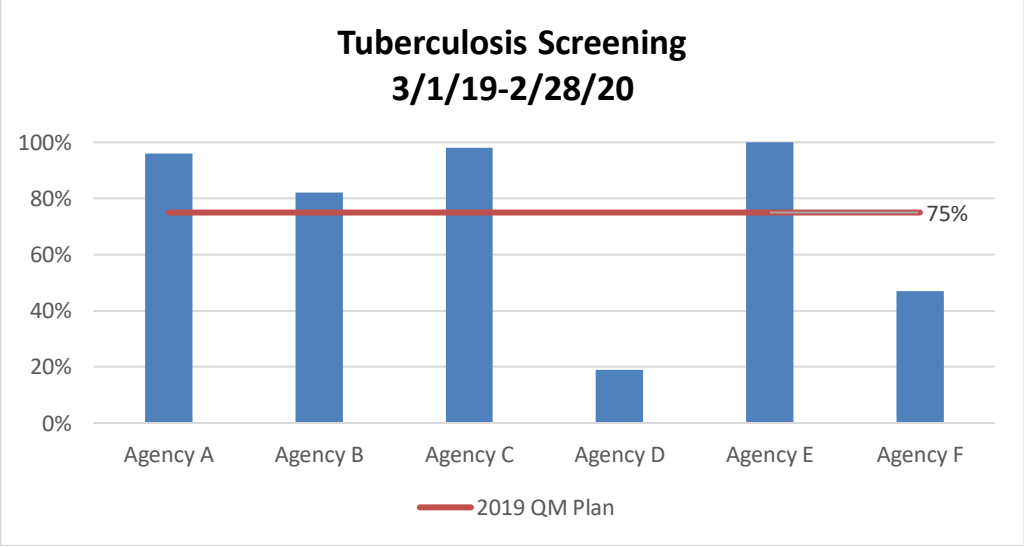


Tuberculosis Screening

- Percent of clients living with HIV who received testing with results documented for LTBI with any approved test (tuberculin skin test [TST] or interferon gamma release assay [IGRA]) since HIV diagnosis

	2017	2018	2019
Number of clients who received documented testing for LTBI with any approved test (tuberculin skin test [TST] or interferon gamma release assay [IGRA]) since HIV diagnosis	375	401	426
Number of clients who: • do not have a history of previous documented culture-positive TB disease or previous documented positive TST or IGRA; and • had a medical visit with a provider with prescribing privileges at least twice in the measurement year.	558	565	570
Rate	**67.2%**	**71%**	**74.7%**
Change from Previous Years Results	**.3%**	**3.8%**	**3.7%**

2019 TB Screening by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who received documented testing for LTBI with any approved test (tuberculin skin test [TST] or interferon gamma release assay [IGRA]) since HIV diagnosis	164	173	79
Number of clients who: • do not have a history of previous documented culture-positive TB disease or previous documented positive TST or IGRA; and • had a medical visit with a provider with prescribing privileges at least once in the measurement year.	250	213	97
Rate	**65.6%**	**81.2%**	**81.4%**



Adolescent/Adult Performance Measures

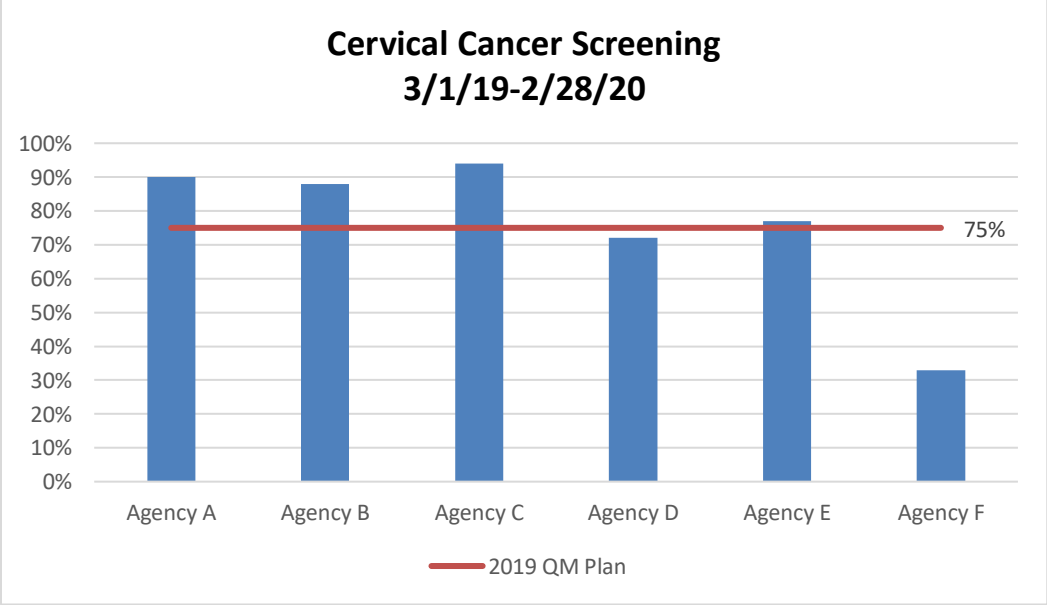
Cervical Cancer Screening

- Percentage of women living with HIV who have Pap screening results documented in the previous three years

	2017	2018	2019
Number of female clients who had Pap screen results documented in the previous three years	226	199	214
Number of female clients: • for whom a pap smear was indicated, and • who had a medical visit with a provider with prescribing privileges at least twice in the measurement year*	274	244	260
Rate	**82.5%**	**81.6%**	**82.3%**
Change from Previous Years Results	**2.4%**	**-.9%**	**.7%**

- 16.4% (35/214) of pap smears were abnormal

2019 Cervical Cancer Screening Data by Race/Ethnicity			
	Black	Hispanic	White
Number of female clients who had Pap screen results documented in the previous three years	131	70	11
Number of female clients: • for whom a pap smear was indicated, and • who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	148	90	19
Rate	**88.5%**	**77.8%**	**57.9%**



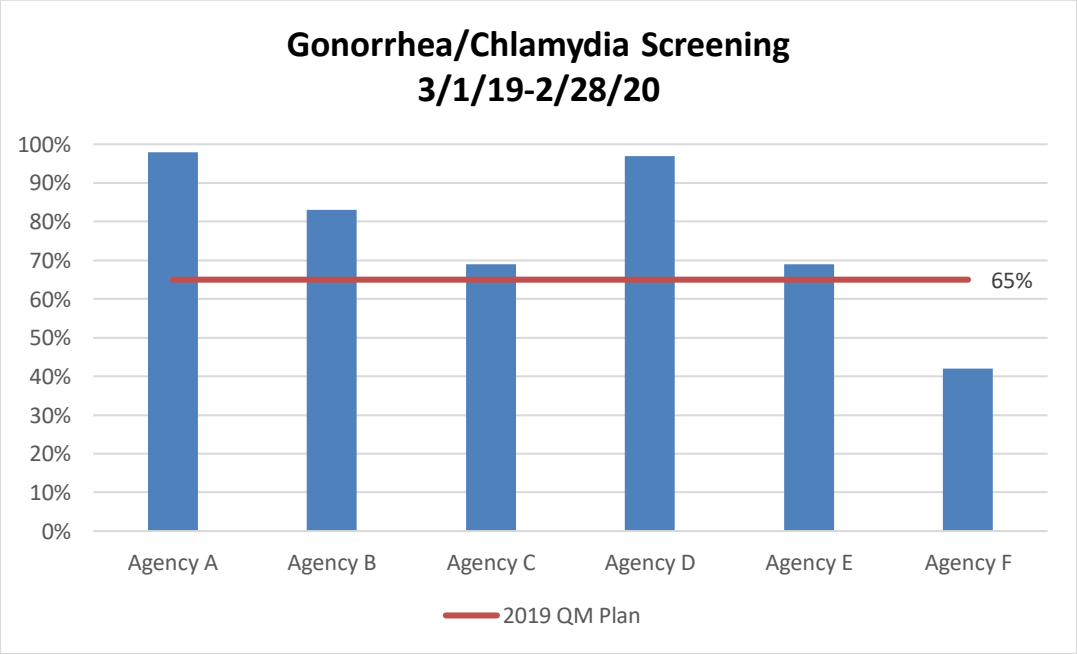
Gonorrhea/Chlamydia Screening

- Percent of clients living with HIV at risk for sexually transmitted infections who had a test for Gonorrhea/Chlamydia within the measurement year

	2017	2018	2019
Number of clients who had a test for Gonorrhea/Chlamydia	493	501	506
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	635	635	635
Rate	**77.6%**	**78.9%**	**79.7%**
Change from Previous Years Results	**4.7%**	**1.3%**	**.8%**

- 24 cases of chlamydia and 23 cases of gonorrhea were identified

2019 GC/CT by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who had a serologic test for syphilis performed at least once during the measurement year	224	195	79
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	272	247	105
Rate	**82.4%**	**78.9%**	**75.2%**



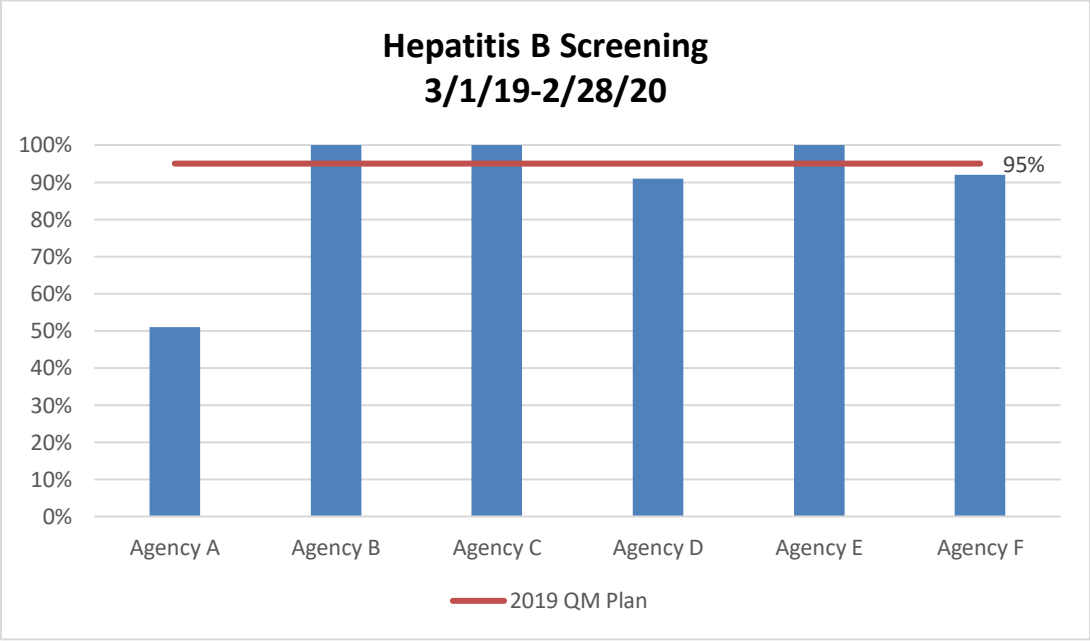
Hepatitis B Screening

- Percentage of clients living with HIV who have been screened for Hepatitis B virus infection status

	2017	2018	2019
Number of clients who have documented Hepatitis B infection status in the health record	553	577	571
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	635	635	635
Rate	**87.1%**	**90.9%**	**89.9%**
Change from Previous Years Results	**-9%**	**3.8%**	**-1%**

- 1.3% (8/635) were Hepatitis B positive

2019 Hepatitis B Screening by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who have documented Hepatitis B infection status in the health record	252	215	93
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	272	247	105
Rate	**92.6%**	**87%**	**88.6%**

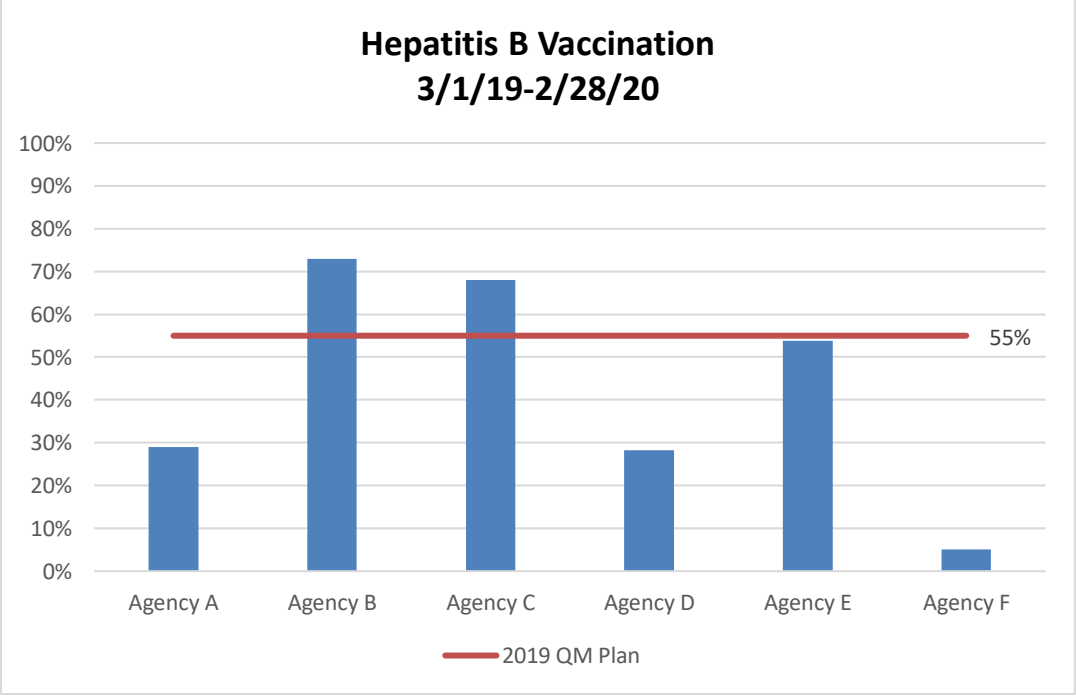


Hepatitis B Vaccination

- Percentage of clients living with HIV who completed the vaccination series for Hepatitis B

	2017	2018	2019
Number of clients with documentation of having ever completed the vaccination series for Hepatitis B	196	171	177
Number of clients who are Hepatitis B Nonimmune and had a medical visit with a provider with prescribing privileges at least twice in the measurement year	381	347	342
Rate	**51.4%**	**49.3%**	**51.8%**
Change from Previous Years Results	**-4.2%**	**-2.1%**	**2.5%**

2019 Hepatitis B Vaccination by Race/Ethnicity			
	Black	Hispanic	White
Number of clients with documentation of having ever completed the vaccination series for Hepatitis B	52	95	27
Number of clients who are Hepatitis B Nonimmune and had a medical visit with a provider with prescribing privileges at least twice in the measurement year	120	161	55
Rate	**43.3%**	**59%**	**49.1%**



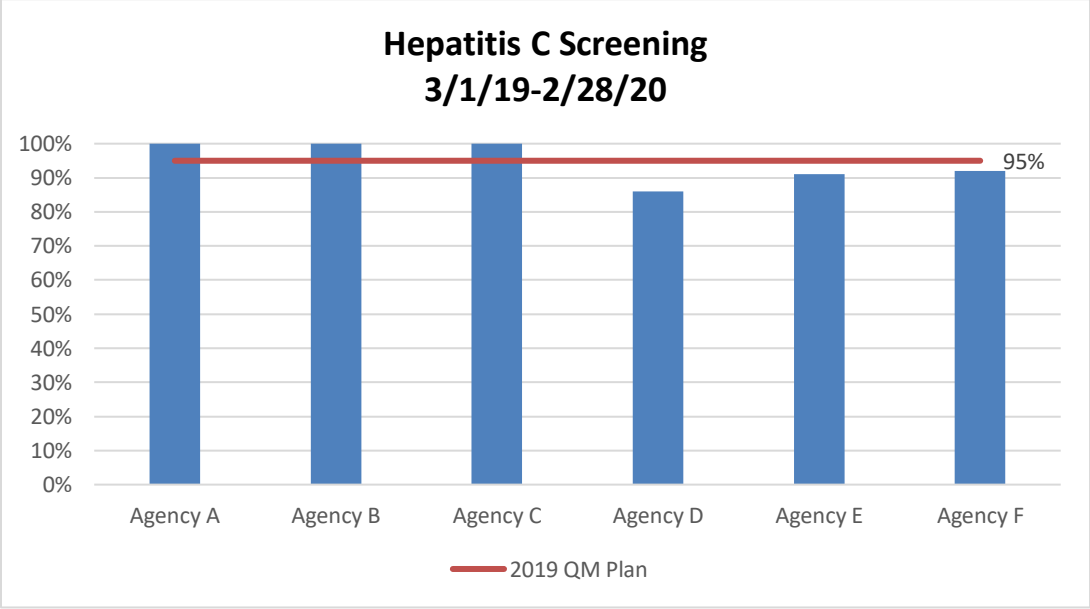
Hepatitis C Screening

- Percentage of clients living with HIV for whom Hepatitis C (HCV) screening was performed at least once since diagnosis of HIV

	2017	2018	2019
Number of clients who have documented HCV status in chart	589	604	612
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	635	635	635
Rate	**92.8%**	**95.1%**	**96.4%**
Change from Previous Years Results	**-6.3%**	**2.3%**	**1.3%**

- 7.9% (50/635) were Hepatitis C positive, including 11 acute infections only and 30 cures (76.9%)

2019 Hepatitis C Screening by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who have documented HCV status in chart	257	240	104
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	272	247	105
Rate	**94.5%**	**97.1%**	**99%**

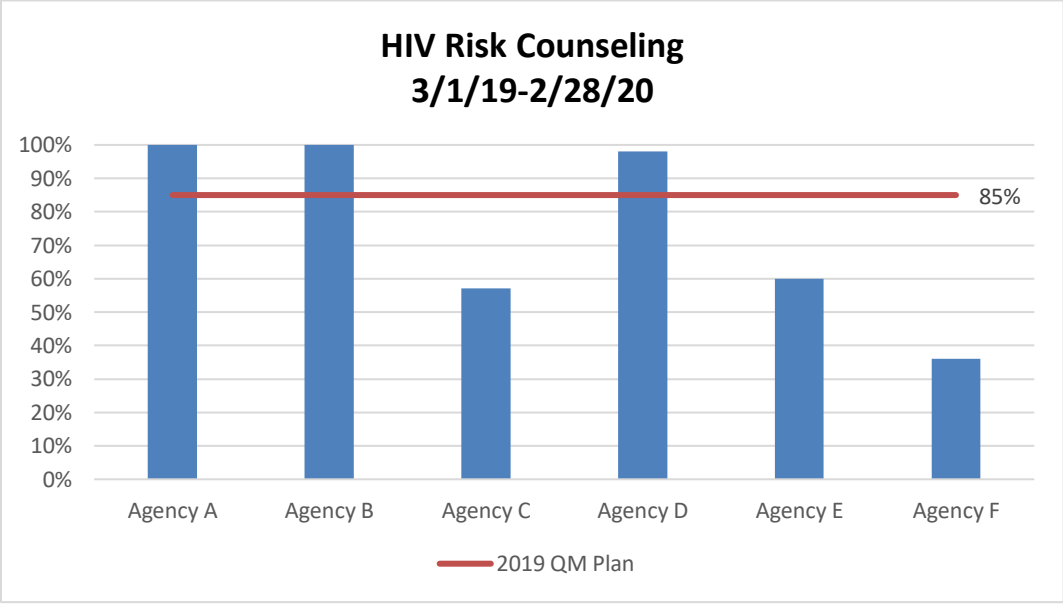


HIV Risk Counseling

- Percentage of clients living with HIV who received HIV risk counseling within measurement year

	2017	2018	2019
Number of clients, as part of their primary care, who received HIV risk counseling	576	533	520
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	635	635	635
Rate	**90.7%**	**83.9%**	**81.9%**
Change from Previous Years Results	**21.3%**	**-6.8%**	**-2%**

2019 HIV Risk Counseling by Race/Ethnicity			
	Black	Hispanic	White
Number of clients, as part of their primary care, who received HIV risk counseling	228	208	76
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	272	247	105
Rate	**83.8%**	**84.2%**	**72.4%**

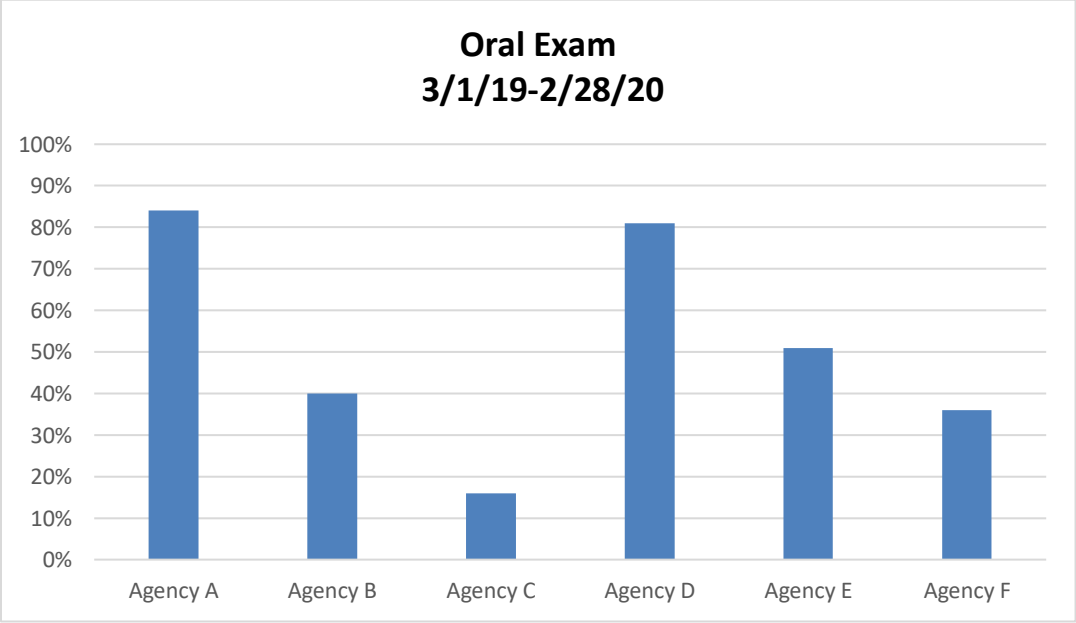


Oral Exam

- Percent of clients living with HIV who were referred to a dentist for an oral exam or self-reported receiving a dental exam at least once during the measurement year

	2017	2018	2019
Number of clients who were referred to a dentist for an oral exam or self-reported receiving a dental exam at least once during the measurement year	272	355	291
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	635	635	635
Rate	**42.8%**	**55.9%**	**45.8%**
Change from Previous Years Results	**-8.7%**	**13.1%**	**-10.1%**

2019 Oral Exam by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who were referred to a dentist for an oral exam or self-reported receiving a dental exam at least once during the measurement year	130	115	41
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	272	247	105
Rate	**47.8%**	**46.6%**	**39%**



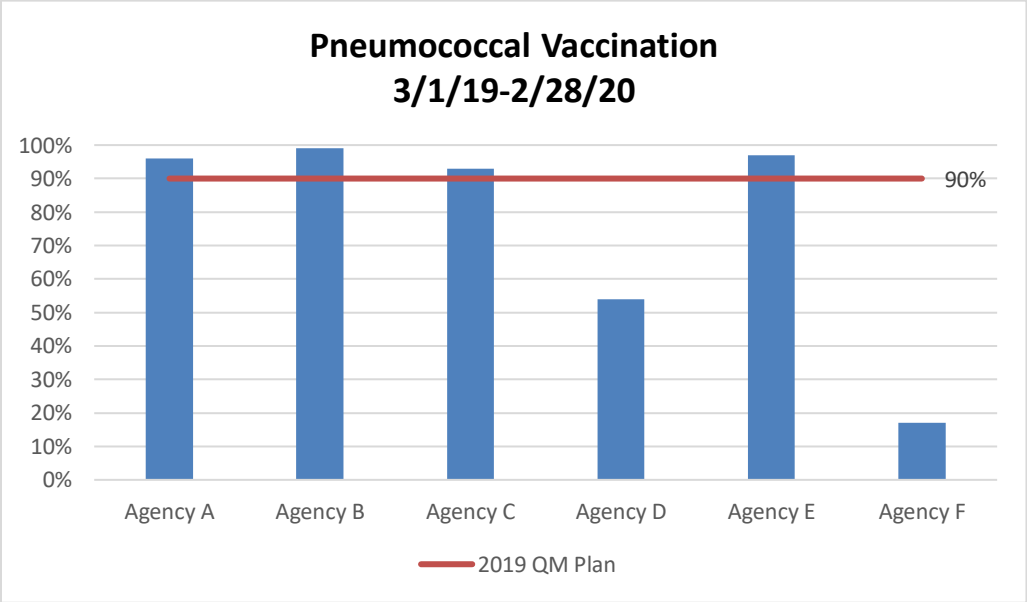
Pneumococcal Vaccination

- Percentage of clients living with HIV who ever received pneumococcal vaccination

	2017	2018	2019
Number of clients who received pneumococcal vaccination	514	507	523
Number of clients who: • had a CD4 count > 200 cells/mm3, and • had a medical visit with a provider with prescribing privileges at least twice in the measurement period	616	610	612
Rate	**83.4%**	**83.1%**	**85.5%**
Change from Previous Years Results	**-3.3%**	**-.3%**	**2.4%**

- 363 clients (59.3%) received both PPV13 and PPV23 (FY18- 65.1%, FY17- 60.5%)

2019 Pneumococcal Vaccination by Race/Ethnicity			
	Black	Hispanic	White
Number of clients who received pneumococcal vaccination	216	216	82
Number of clients who: • had a CD4 count > 200 cells/mm3, and had a medical visit with a provider with prescribing privileges at least twice in the measurement period	262	239	101
Rate	**82.4%**	**90.4%**	**81.2%**

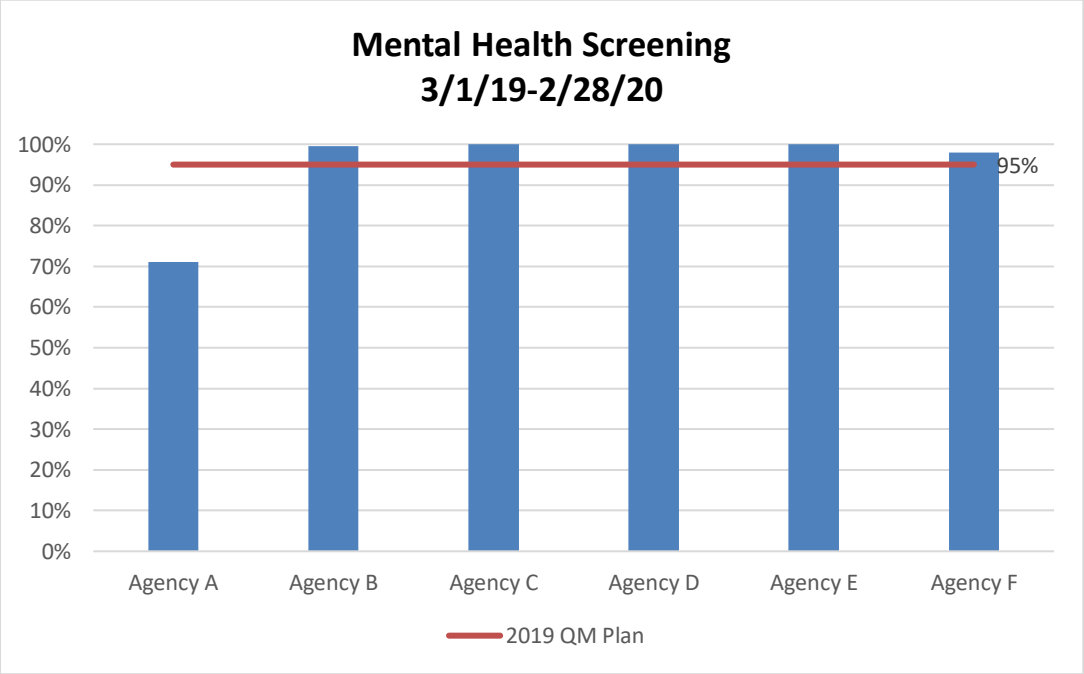


Preventative Care and Screening: Mental Health Screening

- Percentage of clients living with HIV who have had a mental health screening

	2017	2018	2019
Number of clients who received a mental health screening	612	623	604
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement period	635	635	635
Rate	**96.4%**	**98.1%**	**95.1%**
Change from Previous Years Results	**8.5%**	**1.7%**	**-3%**

- 27.2% (173/635) had mental health issues. Of the 90 who needed additional care, 82 (91.1%) were either managed by the primary care provider or referred; 8 clients refused a referral.

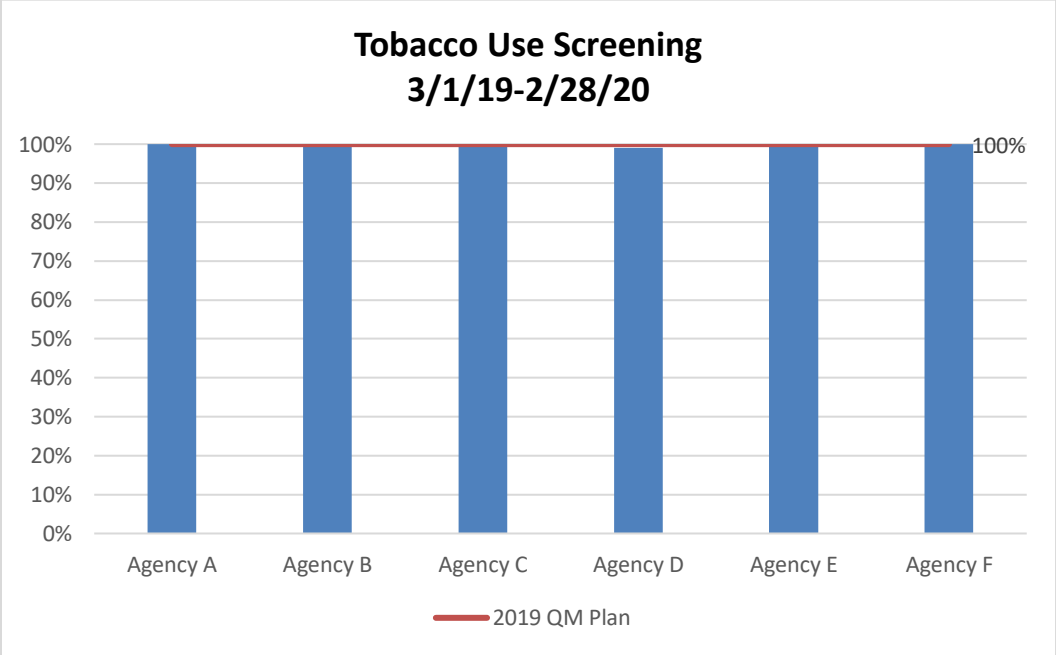


Preventative Care and Screening: Tobacco Use: screening & cessation intervention

- Percentage of clients living with HIV who were screened for tobacco use one or more times with 24 months and who received cessation counseling if indicated

	2017	2018	2019
Number of clients who were screened for tobacco use in the measurement period	635	627	634
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement period	635	635	635
Rate	**100%**	**98.7%**	**99.8%**
Change from Previous Years Results	**.6%**	**-1.3%**	**1.1%**

- Of the 634 clients screened, 153 (24.1%) were current smokers.
- Of the 153 current smokers, 104 (68%) received smoking cessation counseling, and 11 (7.2%) refused smoking cessation counseling



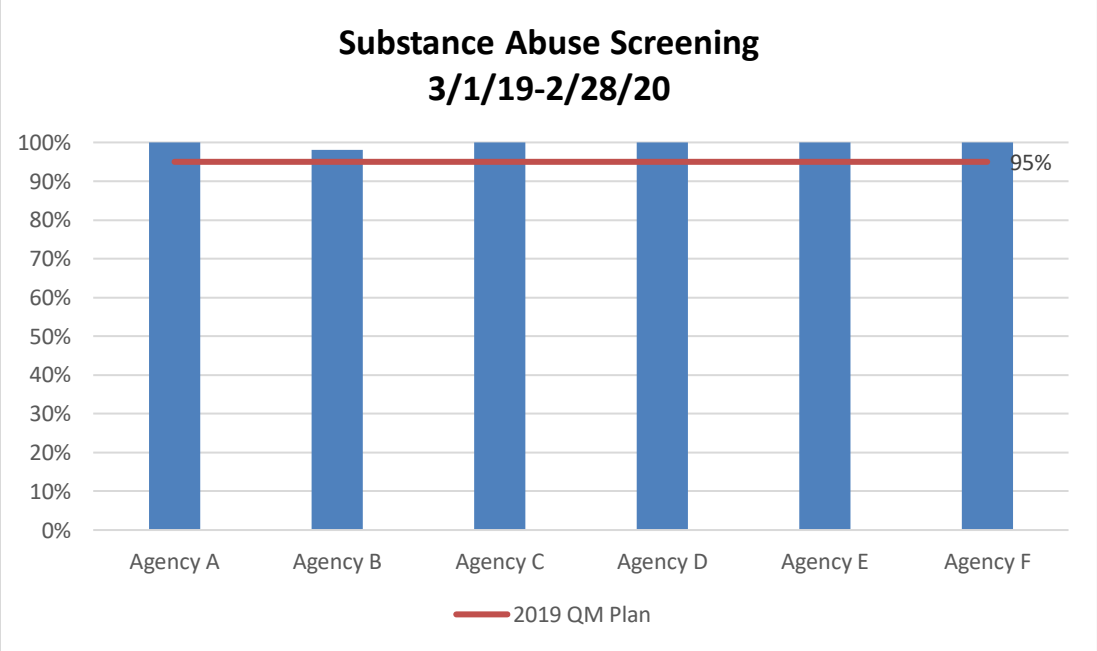
Substance Use Screening

- Percentage of clients living with HIV who have been screened for substance use (alcohol & drugs) in the measurement year*

	2017	2018	2019
Number of new clients who were screened for substance use within the measurement year	629	631	632
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement period	635	635	635
Rate	**99.1%**	**99.4%**	**99.5%**
Change from Previous Years Results	**.5%**	**.3%**	**.1%**

*HAB measure indicates only new clients be screened. However, Houston EMA standards of care require medical providers to screen all clients annually.

- 4.3% (27/635) had a substance use disorder. Of the 27 clients who needed referral, 16 (59.3%) received one, and 10 (37%) refused.

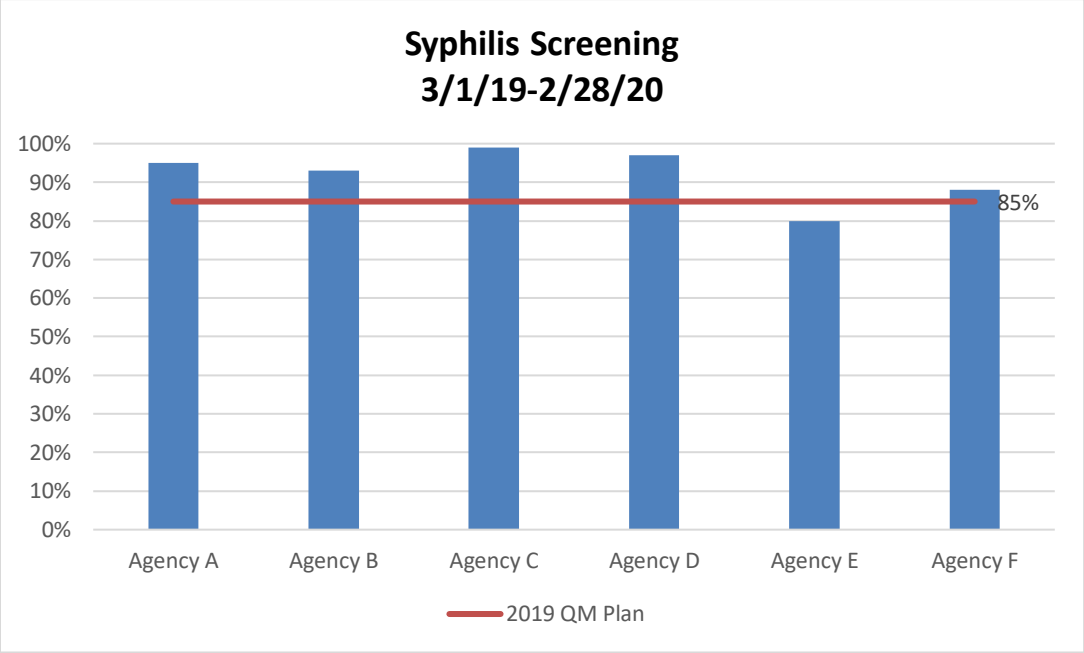


Syphilis Screening

- Percentage of clients living with HIV who had a test for syphilis performed within the measurement year

	2017	2018	2019
Number of clients who had a serologic test for syphilis performed at least once during the measurement year	587	602	600
Number of clients who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	635	635	635
Rate	**92.4%**	**94.8%**	**94.5%**
Change from Previous Years Results	**-1.6%**	**2.4%**	**-.3%**

- 7.1% (45/635) new cases of syphilis diagnosed

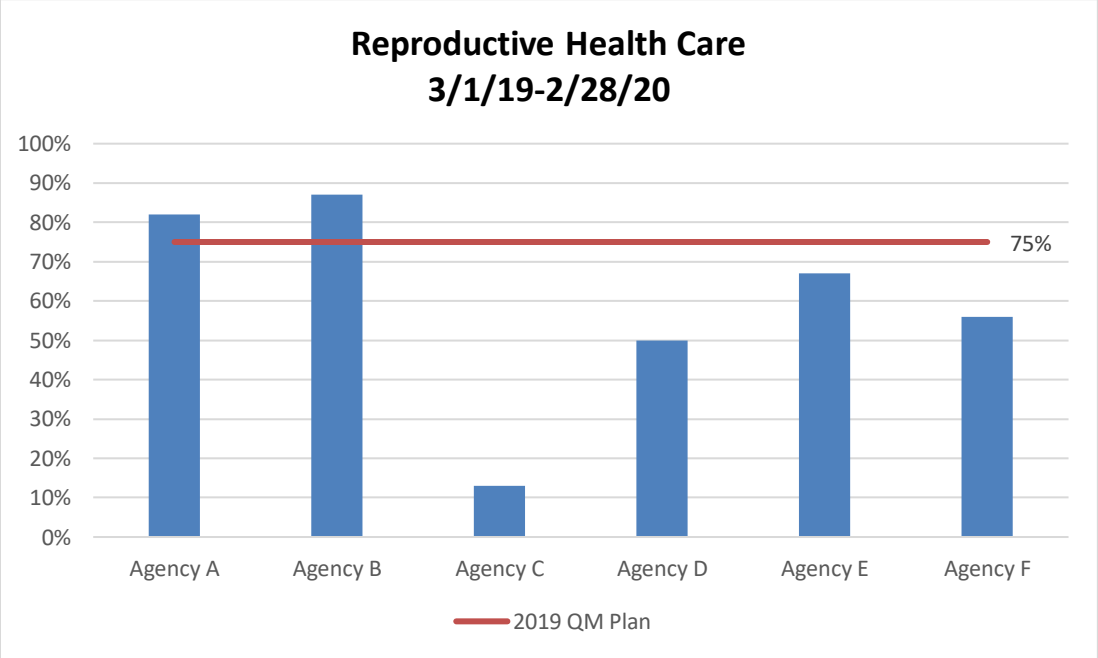


Other Measures

Reproductive Health Care

- Percentage of reproductive-age women living with HIV who received reproductive health assessment and care (i.e, pregnancy plans and desires assessed and either preconception counseling or contraception offered)

	2017	2018	2019
Number of reproductive-age women who received reproductive health assessment and care	22	29	37
Number of reproductive-age women who: • did not have a hysterectomy or bilateral tubal ligation, and • had a medical visit with a provider with prescribing privileges at least twice in the measurement period	63	54	66
Rate	**34.9%**	**53.7%**	**56.1%**
Change from Previous Years Results	**-19.1%**	**18.8%**	**2.4%**

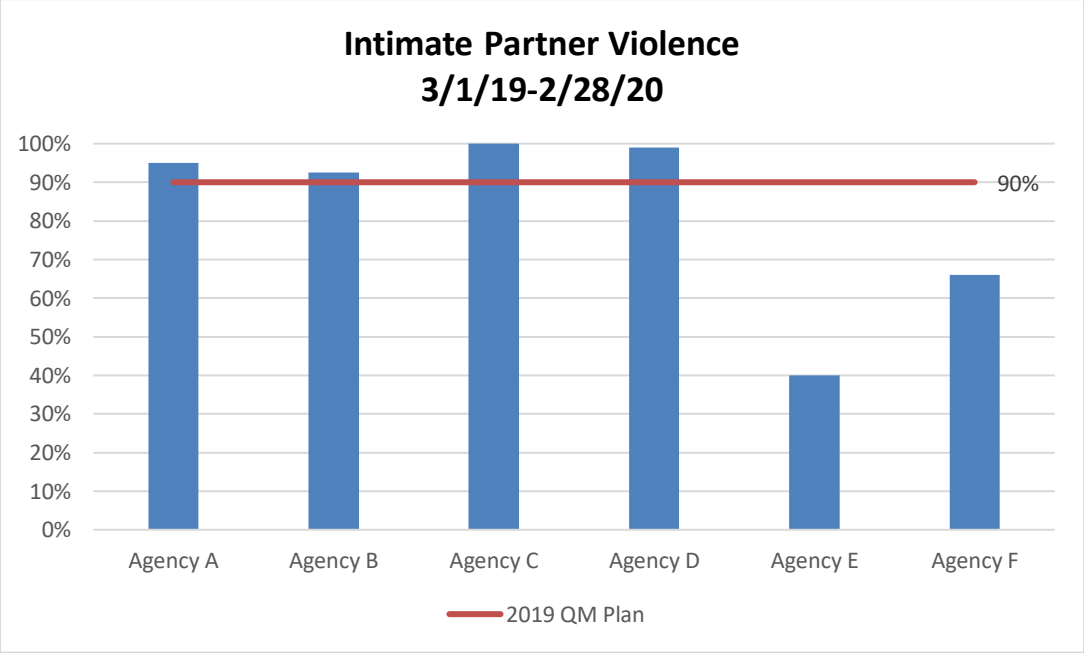


Intimate Partner Violence Screening

- Percentage of clients living with HIV who received screening for current intimate partner violence

	2017	2018	2019
Number of clients who received screening for current intimate partner violence	499	592	577
Number of clients who: • had a medical visit with a provider with prescribing privileges at least twice in the measurement period	635	635	635
Rate	**78.6%**	**93.2%**	**90.9%**
	-3.3%	**14.6%**	**-2.3%**

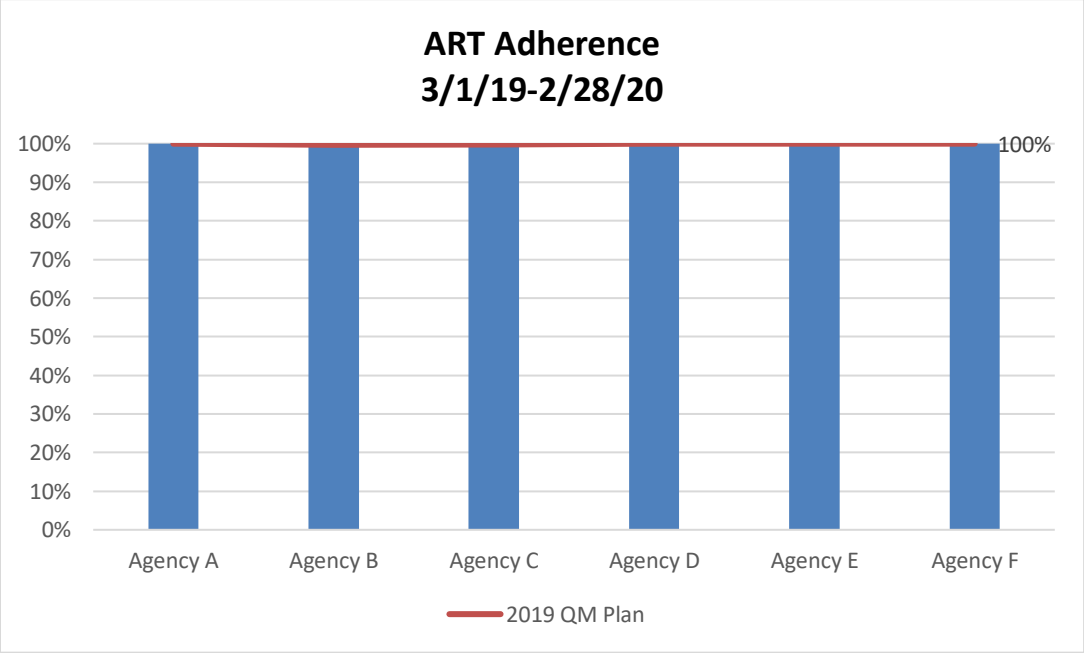
* 4/635 screened positive



Adherence Assessment & Counseling

- Percentage of clients living with HIV on ART who were assessed for adherence at least once per year

	Adherence Assessment		
	2017	2018	2019
Number of clients, as part of their primary care, who were assessed for adherence at least once per year	627	631	627
Number of clients on ART who had a medical visit with a provider with prescribing privileges at least twice in the measurement year	627	631	627
Rate	**100%**	**100%**	**100%**
Change from Previous Years Results	**.5%**	**0%**	**0%**



ART for Pregnant Women

- Percentage of pregnant women living with HIV who are prescribed antiretroviral therapy (ART)

	2017	2018	2019
Number of pregnant women who were prescribed ART during the 2nd and 3rd trimester	3	3	2
Number of pregnant women who had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year	3	3	2
Rate	**100%**	**100%**	**100%**
Change from Previous Years Results	**0%**	**0%**	**0%**

Primary Care: Diabetes Control

- Percentage of clients living with HIV and diabetes who maintained glucose control during measurement year

	2017	2018	2019
Number of diabetic clients whose last HbA1c in the measurement year was <8%	48	35	38
Number of diabetic clients who had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year	74	67	65
Rate	**64.9%**	**52.2%**	**58.5%**
Change from Previous Years Results	**-8%**	**-12.7%**	**6.3%**

- 635/635 (100%) of clients where screened for diabetes and 65/635 (10.2%) were diagnosed diabetic

Primary Care: Hypertension Control

- Percentage of clients living with HIV and hypertension who maintained blood pressure control during measurement year

	2017	2018	2019
Number of hypertensive clients whose last blood pressure of the measurement year was <140/90	166	145	147
Number of hypertensive clients who had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year	206	180	181
Rate	**80.6%**	**80.6%**	**81.2%**
Change from Previous Years Results	**6.7%**	**0%**	**.6%**

- 181/635 (28.5%) of clients were diagnosed with hypertension

Primary Care: Breast Cancer Screening

- Percentage of women living with HIV, over the age of 41, who had a mammogram or a referral for a mammogram, in the previous two years

	2017	2018	2019
Number of women over age 41 who had a mammogram or a referral for a mammogram documented in the previous two years	150	141	142
Number of women over age 41 who had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year	171	164	167
Rate	**87.7%**	**86%**	**85%**
Change from Previous Years Results	**13.8%**	**-1.7%**	**-1%**

Primary Care: Colon Cancer Screening

- Percentage of clients living with HIV, over the age of 50, who received colon cancer screening (colonoscopy, sigmoidoscopy, or fecal occult blood test) or a referral for colon cancer screening

	2017	2018	2019
Number of clients over age 50 who had colon cancer screening or a referral for colon cancer screening	93	127	123
Number of clients over age 50 who had a medical visit with a provider with prescribing privileges, i.e. MD, PA, NP at least twice in the measurement year	151	160	173
Rate	**61.6%**	**79.4%**	**71.1%**
Change from Previous Years Results	**7.7%**	**17.8%**	**-8.3%**

Conclusions

The Houston EMA continues to demonstrate high quality clinical care. Overall, performance rates were comparable to the previous year. However, Viral Load Suppression has slightly increased, as has Influenza, Pneumococcal, and Hepatitis B Vaccination. Mental Health Screening experienced a decrease in performance. Racial and ethnic disparities continue to be seen, particularly for viral load suppression rates. Eliminating racial and ethnic disparities in care are a priority for the EMA, and will continue to be a focus for quality improvement.

Harris County
Public Health
Building a Healthy Community

Ryan White Part A
Quality Management Program- Houston EMA
Case Management Chart Review FY 19-20
Ryan White Grant Administration

CUMMULATIVE SUMMARY, DE-IDENTIFIED

Table of Contents

Overview

Each year, the Ryan White Grant Administration Quality Management team conducts chart review in order to continuously monitor case management services and understand how each agency implements workflows to meet quality standards for their funded service models. This process is a supplemental complement to the programmatic and fiscal audit of each program, as it helps to provide an overall picture of quality of care and monitor quality performance measures.

A total of 661 medical case management client records were reviewed across seven of the ten Ryan White-Part A funded agencies, including a non-primary care site that provides Clinical Case Management services. The dates of service under review were March 1, 2019- February 28, 2020. The sample selection process and data collection tool are described in subsequent sections.

Case Management is defined by the Ryan White legislation as a, “range of client-centered services that link clients with health care, psychosocial, and other services,” including coordination and follow-up of medical treatment and “adherence counseling to ensure readiness for and adherence to HIV complex treatments.” Case Managers assist clients in navigating the complex health care system to ensure coordination of care for the unique needs of People Living With HIV. Continuous assessment of need and the development of individualized service plans are key components of case management. Due to their training and skill sets in social services, human development, psychology, social justice, and communication, Case Managers are uniquely positioned to serve clients who face environmental and life issues that can jeopardize their success in HIV treatment, namely, mental health and substance abuse, poverty and access to stable housing and transportation, and poor social support networks.

Ryan White Part-A funds three distinct models of case management: Medical Case Management, Non-Medical Case Management (or Service Linkage Work), and Clinical Case Management, which must be co-located in an agency that offers Mental Health treatment/counseling and/or Substance Abuse treatment. Some agencies are also funded for Outreach Services, which complement Case Management Services and are designed to locate and assist clients who are on the cusp of falling out of care in order to re-engage and retain them back into care.

The Tool

A copy of the Case Management Chart Review tool is available in the Appendix of this report.

The Case Management Chart Review tool is a pen and paper form designed to standardize data collection and analysis across agencies. The purpose of the tool is to capture information and quantify services that can present an overall picture of the quality of case management services provided within the Ryan White Part-A system of care. This way, strengths and areas of improvement can be identified and continuously monitored.

The coversheet of the chart abstraction tool captures basic information about the client, including their demographics, most recent appointments and lab results, and any documented psychological, medical, or social issues or conditions that would be documented in their medical record.

The content of the second sheet focuses on coordination of case management services. There is space for the chart abstractor to record what type of worker assisted the client (Medical Case Manager, Service Linkage Worker, Outreach Worker or Clinical Case Manager) and what types of services were provided. Any notes about case management closure are recorded, as well as any assessments or service plans or documented reasons for the absence of assessments or service plans.

The Sample

In order to conduct a thorough and comprehensive review, a total of 661 client records were reviewed across seven agencies for the 2019-2020 grant year. This included eighty-four (84) Clinical Case Management charts at a non-primary care site. In this Case Management Chart Review Report, any section that evaluated a primary care related measure excludes the sample of the non-primary care site. Minimum sample size was determined in accordance with *Center for Quality Improvement & Innovation* sample size calculator[2] based on the total eligible population that received case management services at each site.

Agency	A	B	C	D	E	F	G
# of Charts Reviewed	105	105	105	97	79	86	84

TOTAL 661 (577 excluding non-PCare site)

For each agency, a randomized sample of clients who received a billable Ryan White- A service under at least one (1) of eleven (11) case management subcategory codes during the March 1, 2019- February 28, 2020 grant year was queried from the Centralized Patient Care Data Management System data base. Each sample was determined to be comparable to the racial, ethnic, age, and gender demographics of each site's overall case management patient population.

Cumulative Data Summaries

APPOINTMENTS & ENCOUNTERS

The number of HIV-related primary care appointments and case management encounters in the given year were counted for each client.

HIV-RELATED PRIMARY CARE APPOINTMENTS

For this measure, the number of face-to-face encounters for an HIV-related primary care appointment with a medical provider was counted. Any number of appointments above three per year was simply coded as 3 appointments. Any Viral Load/CD4 count lab test that accompanied the appointment was also recorded.

HIV MEDICAL # appt	A	B	C	D	E	F	TOTAL	PERCENT
0	10	10	16	16	4	14	70	**12%**
1	22	13	18	4	21	18	96	**17%**
2	39	20	16	8	20	15	118	**20%**
3	34	62	55	69	34	39	293	**51%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*577*	

The overall sample trends towards a higher number of primary care appointment in the year, with the majority of the case management review clients having at least 3 appointments in the year (51%), followed by 20% of the clients having 2 appointments in the year.

CASE MANAGEMENT ENCOUNTERS

Frequency of case management encounters were also reviewed. The number and types of the encounters (face-to-face vs. phone), as well as who provided the service (Clinical, Medical, Non-Medical Case Manager or Outreach Worker) were also recorded.

The distribution of frequency of case management encounters could be described as an inverted bell curve, with most of the clients clustering either at the low end of one encounter (33%) within the year or more than 5 encounters (26%).

*"Overall, the average number of case management encounters for the entire sample was **three (3)**."*

CASE MGMNT # appointments	A	B	C	D	E	F	G	TOTAL	PERCENT
1	39	32	36	31	30	27	25	220	**33%**
2	24	26	19	16	15	12	11	123	**19%**
3	18	13	14	13	10	13	6	87	**13%**
4	11	8	10	12	7	6	3	57	**9%**
5	13	26	26	25	17	28	39	174	**26%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*84*	*661*	

VIRAL SUPPRESSION

Any results of HIV Viral Load + CD4 count laboratory tests that accompanied HIV-related primary care appointments were recorded as part of the case management chart abstraction. Up to three laboratory tests could be recorded. Lab results with an HIV viral load result of less than 200 copies per milliliter were considered to be virally suppressed.

Upon coding, clients who were suppressed for all of their recorded labs (whether they had one, two, or three tests done within the year), were coded as "Suppressed." Clients who were unsuppressed (>200 copies/mL) for all of their labs were coded as "Unsuppressed." Clients who had more than one laboratory test done and were suppressed for at least one and unsuppressed for at least one were coded as "Mixed Status," and clients who had no laboratory tests done within the entire year were coded as "Unknown."

SUPPRESSION STATUS	A	B	C	D	E	F	TOTAL	PERCENT
Suppressed for all labs	69	64	68	54	51	64	370	**64%**
Mixed status	10	12	9	13	14	6	64	**11%**
Unknown (no recent labs on file)	13	10	18	18	7	13	79	**14%**
Unsuppressed for all labs	13	19	10	12	7	3	64	**11%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*577*	

Across all primary care sites, the case management clients reviewed for these samples had a viral load suppression rate of 64%. In contrast, this result is much lower than what is typical for the Ryan White Part A Houston Primary Care Chart review, which has hovered around 85% for the past several years. This difference may be due to a number of factors, most likely of which is the difference in characteristics of the two reviews' samples. The Primary Care chart review sample is collected from a pool of clients who are considered *in care*, or have at least two medical appointments with a provider with prescribing privileges in the review year. Additionally, "fluctuating viral load" is one of the eligibility criteria for medical case management, so clients who have challenges maintaining a suppressed viral load are more likely to be seen by case management and be included in this sample.

CARE STATUS

The chart abstractor also documented any circumstances in the record for which a client was new, lost, returning to care, or some combination of those care statuses. A client was considered "New to Care," if they were receiving services for the first time at that particular agency (so not necessarily new to HIV treatment or the Houston Ryan White system of care). "Lost to Care" was defined as not being seen for an HIV-related primary care appointment within the last six months and not having a future appointment scheduled, even beyond the review year. "Re-engaged in Care" was defined as any client who was previously lost to care, either during or before the review year, and later attended an HIV-related primary care appointment.

CARE STATUS	A	B	C	D	E	F	TOTAL	PERCENT
New to Care	4	2	7	4	6	5	28	**5%**
Lost to Care	7	12	13	3	3	8	46	**8%**
Re-engaged in Care	7	14	8	6	10	0	45	**8%**
Both New and later Lost to Care in the same review year	1	0	1	0	0	0	2	**<1%**
Re-engaged and later lost again	1	3	0	3	0	2	9	**2%**
N/A	85	77	76	80	60	71	449	**78%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*577*	

Overall, 5% of the sample was considered New to Care, 8% was Lost to Care, and 8% was Re-engaged in Care.

When a client's attendance met one of the above care statuses, their medical record was reviewed to understand if case management or other staff was involved in coordinating their care. Activities that counted as "Coordination of Care" were any actions that welcomed the client into or back into care or attempted to retain them in care, such as: reminder phone calls, follow-up calls, attendance or introduction at the first appointment, or home visits. For agencies funded for Outreach Services, several progress notes appeared for clients who were lost or re-engaged in care.

COMORBIDITIES

In an effort to understand and document common comorbidities within the Houston Ryan White system of care, co-occurring conditions were recorded, including mental health and substance abuse issues, other medical conditions, and social conditions. This inventorying of co-morbidities may prove particularly helpful for selecting future training topics for case management staff.

MENTAL HEALTH & SUBSTANCE USE DISORDER (history or active)

Any diagnosis of a mental health disorder (MH) or substance use disorder issue (SUD) was recorded in the chart review tool, including a history of mental illness or substance use. All Electronic Medical Records include some variation of a "Problem List" template. This list was often a good source of information for MH and SUD diagnoses, but providers sometimes also documented diagnoses or known histories of illness within progress notes without updating the Problem List. Clients sometimes also self-reported that they had been diagnosed with one of the below conditions by a previous medical provider. Any indication of the presence of mental illness or SUD, regardless of where the information was housed within the medical record, was recorded on the chart abstraction tool. Clients could also have or have had more than one of the MH or SUD issues. Any conditions other than alcohol misuse, other SUD, depression, bipolar disorder, anxiety, or schizophrenia were recorded as "Other." The most common types of conditions that became coded as "Other" were Post-Traumatic Stress Disorder and Adjustment Disorder.

Diagnosis or Issue	A	B	C	D	E	F	G	TOTAL	PERCENT
Alcohol abuse/dependence	5	6	3	4	3	3	11	35	**5%**
Other Substance dependence	17	18	19	16	11	4	19	104	**16%**
Depression	25	41	32	26	13	15	39	191	**29%**
Bipolar disorder	10	6	4	5	4	3	12	44	**7%**
Anxiety	4	21	11	16	8	12	29	101	**15%**
Schizophrenia	4	1	2	0	0	2	6	15	**2%**
Other	11	16	16	29	4	4	15	95	**14%**

Overall, 41% of the sample had either an active diagnosis or history of a mental health or substance abuse issue documented somewhere within their medical record. This is inclusive of the Clinical Case Management site, for which diagnosis with or clinical indication of a MH or SUD issue is an eligibility criteria.

MENTAL HEALTH & SUBSTANCE USE DISORDER REFERRALS

For clients with an *active* diagnosis of a mental health or SUD issue, the chart abstractor recorded if they were referred or already engaged in MH/SUD services. This measure was *not* inclusive of clients who had a previous history of symptoms or whose recovery treatment was considered long complete. Because of this, the percentage in the top row of the previous chart and the percentage of clients considered "N/A" for a MH/SA referral do not equal 100%.

MH referral	A	B	C	D	E	F	TOTAL	PERCENT
N/A	70	54	65	56	57	63	365	**63%**
Yes	28	42	34	34	20	19	177	**31%**
No	7	9	6	7	2	4	35	**6%**
Total	105	105	105	97	79	86	577	

Overall, 63% of the sample would not have been appropriate for a MH or SUD referral based on the information available in their medical record. An additional 31% either did receive a referral or were already engaged in treatment and 6% did not receive a referral.

MEDICAL CONDITIONS

Medical conditions other than HIV were also recorded in an effort to understand what co-occurring conditions may be considered commonly managed alongside HIV within the case management population. Sexually Transmitted Infections and Hypertension were common, at 24% and 23% prevalence within the sample, respectively. Obesity was the most common co-occurring condition that was coded in the "Other" category.

Medical Condition	A	B	C	D	E	F	TOTAL	PERCENT
Smoking (hx or current)	54	31	18	12	10	5	130	**23%**
Opportunistic Infection	3	2	1	1	1	2	10	**2%**
STIs	20	37	28	19	23	9	136	**24%**
Diabetes	16	18	9	11	3	9	66	**11%**
Cancer	1	1	0	0	0	0	2	**0%**
Hepatitis	18	8	3	3	2	3	37	**6%**
Hypertension	43	24	20	22	9	17	135	**23%**
Other	8	33	21	24	11	30	127	**22%**

SOCIAL CONDITIONS

Any indication within the medical record that a client had experienced homelessness/housing-related issues, pregnancy/pregnancy-related issues, a release from jail or prison, or intimate partner violence at any point within the review year was recorded in the chart abstraction tool. Homelessness and housing issues were the most commonly identified "Social Condition" within the sample.

Social Issue	A	B	C	D	E	F	G	TOTAL	PERCENT
Homelessness or housing-related issues	6	14	5	4	10	1	6	46	**7%**
Pregnancy or pregnancy-related issues	0	0	1	0	4	2	0	7	**1%**
Recently released	4	3	4	2	3	0	2	18	**3%**
Intimate Partner Violence	1	2	2	1	2	2	12	22	**3%**

COMPREHENSIVE ASSESSMENTS

A cornerstone of service provision within case management is the opportunity for the client to be formally assessed at touchpoints throughout the year for their needs, treatment goals, and action steps for how they will work with the case manager or care team to achieve their treatment goals. Agencies need to use an approved assessment tool and service plan, which may either be the sample tools available through Ryan White Grant Administration or a pre-approved tool of the agency's choosing.

The Ryan White Part-A Standards for medical case management state that a comprehensive assessment should be completed with the client at intake and that they should be re-assessed at least every six months for as long as they are receiving medical case management services. A more formal, comprehensive assessment should be used at intake and annually, and a brief reassessment tool is sufficient at the 6-month mark. In other words, the ideal standard is that every client who receives case management services for an entire year should have at least two comprehensive assessments on file. A service plan should accompany each comprehensive assessment to outline the detailed plan of how the identified needs will be addressed with the client.

# of Comp assessments	A	B	C	D	E	F	G	TOTAL	PERCENT
0	4	13	16	31	5	21	26	116	**18%**
1	1	24	21	12	10	36	23	127	**19%**
2	1	0	3	1	0	4	6	15	**2%**
N/A	99	68	65	53	64	25	31	405	**61%**
Total	105	105	105	97	79	86	84	661	

The client was considered "N/A" for a comprehensive assessment if they did not work with a medical case manager throughout the year. As outlined above, 61% of the sample did not work with a Medical Case Manager within the year. 18% of the sample received zero comprehensive assessments, 19% received one, and 2% received two.

SERVICE PLANS

As mentioned, each comprehensive assessment should be accompanied by a service plan, otherwise known as a care plan, to outline what action will be taken to address the needs that are identified on the comprehensive assessment. A service plan can be thought of as an informal, working contract between client and social worker of who will be accountable for which actions in order for the client to meet their determined treatment goals. As with the comprehensive assessment, each completed service plan was recorded in the chart abstraction tool, along with any documented justification for why a service plan was missing if it should have been completed.

# of service plans	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**TOTAL**	**PERCENT**
0	4	22	26	33	6	29	29	149	**23%**
1	2	15	11	10	9	29	20	96	**15%**
2	0	0	3	1	0	3	6	13	**2%**
N/A	99	68	65	53	64	25	31	405	**61%**
Total	105	105	105	97	79	86	84	661	

It is notable that less service plans are completed than comprehensive assessments, even though the two processes are intended to occur together, one right after the other.

BRIEF ASSESSMENTS

Like Medical Case Management, Non-Medical Case Management is guided by a continuous process of ongoing assessment, service provision, and evaluation. Clients should be assessed at intake using a Ryan White Grant Administration approved brief assessment form and should be reassessed at six-month intervals if they are still being serviced by a Non-Medical Case Manager.

# of Brief assessments	**A**	**B**	**C**	**D**	**E**	**F**	**TOTAL**	**PERCENT**
0	20	33	53	63	5	52	226	**39%**
1	50	43	31	12	47	13	196	**34%**
2	8	1	4	0	4	1	18	**3%**
N/A	27	28	17	22	23	20	137	**24%**
Total	105	105	105	97	79	86	577	

Completion of brief assessments were recorded, along with any justification of why an assessment was not completed if one would have been expected. 24% of the sample would not been applicable for a brief assessment, as they did not receive services from a Non-Medical Case Manager. 39% of the sample received zero brief assessments, 34% received one, and 3% received two.

ASSESSED NEEDS

All data from assessment tools was captured in the chart review tool. A total of 173 Comprehensive Assessments and 211 Brief Assessments were reviewed and recorded in order to quantify the frequency of needs. The count recorded is a raw count of how many times a need was recorded, encompassing both comprehensive and brief assessments and including clients who may have had the same need identified more than once at different points in time.

The most frequently assessed needs were: 1) Medical/Clinical, 2) Dental Care, 3) Vision Care, 4) Medication Adherence Counseling, 5) Mental Health, and (6) Insurance. It should be noted, however, that there are no universal standards or instructions across case management systems on how to use these tools or how these needs are defined. Anecdotally, some case managers reported that they automatically checked "Medical/Clinical" and "Medication Adherence Counseling" as a need, regardless of whether or not the client needed assistance accessing medical care, because it was their understanding that this section *always* needed to be checked in order to justify billing for medical case management services. Therefore, this compilation of comprehensive and brief assessments should not be considered representative of *true need* within the HIV community in Houston, but rather, as representative of issues that case managers are discussing with clients.

Need identified on assessment	A	B	C	D	E	F	G	TOTAL	PERCENT
Medical/Medication	30	17	25	10	38	18	9	147	22%
Vaccinations	5	1	2	0	2	1	0	11	2%
Nutrition/Food Pantry	0	13	4	1	21	4	5	48	7%
Dental	13	22	11	2	30	10	8	96	15%
Vision	13	18	10	3	28	13	3	88	13%
Hearing Care	0	1	0	0	5	1	3	10	2%
Home Health Care	0	1	0	1	4	0	2	8	1%
Basic Necessities/Life Skills	2	11	1	1	8	2	1	26	4%
Mental Health	5	19	9	8	23	13	12	89	13%
Substance Use Disorder	1	8	2	3	8	2	1	25	4%
Abuse	0	0	3	1	4	1	1	10	2%
Housing/Living Situation	3	12	6	5	18	6	18	68	10%
Support Systems	1	5	2	3	14	1	6	32	5%
Child Care	0	0	0	0	0	1	1	2	0%
Insurance	8	6	14	4	33	10	9	84	13%
Transportation	25	12	6	7	17	7	2	76	11%
HIV-Related Legal Assistance	0	2	2	2	2	0	3	11	2%
Cultural/Linguistic	0	0	0	2	1	4	0	7	1%
Self-Efficacy	0	0	0	2	4	2	2	10	2%
HIV Education/Prevention	3	4	3	4	11	1	1	27	4%
Family Planning/ Safer Sex	2	6	4	1	10	1	1	25	4%
Employment	0	3	4	4	9	4	3	27	4%
Education/Vocation	0	0	0	2	7	0	5	14	2%
Financial Assistance	1	5	3	0	16	6	6	37	6%
Medication Adherence Counseling	7	18	18	8	37	19	6	113	17%
Client Strengths	0	1	0	0	3	0	3	7	1%

Conclusion

The 2019-2020 Case Management chart review highlighted many trends about the case management client population, strengths in case management performance, and areas identified for future attention and improvement.

Overall, we continue to learn more about the needs of this patient population by expanding the sample size of the review and adding new elements to the chart abstraction tool. The most common co-occurring conditions were: Sexually Transmitted Infections (24%), Depression (29%), and Hypertension (23%). Diabetes and Obesity were also relatively common and providing overview information on nutrition counseling may be a useful topic for future frontline case management trainings. The prevalence of complex co-morbidities emphasizes the unique benefit that case managers contribute to the HIV treatment setting.

There were also many areas of high performance displayed in this chart review. Most (51%) of the clients in the sample had at least three HIV-related primary care appointments within the review year. Case Management staff demonstrated a high level of coordination of care in many areas. For example, 88% of those with active mental health or substance abuse symptoms either received a referral for further treatment or counseling or were already engaged in services. 87% of the clients who were New, Lost, or Returning to Care (or some combination) received coordination of care activities from case management in an effort to retain them in care.

Appendix (Case Management Chart Review Tool)

CASE MANAGEMENT CHART REVIEW TOOL
Chart Review Date _____/_____/_____
Agency: ☐ AHF ☐ AH ☐ Ave360 ☐ HHS ☐ Legacy ☐ SHF

Review Period:
3/1/20__ - 2/28/20__

CLIENT INFORMATION

Pt. ID # _____ Race: _____

Client Case Status: ☐ Open/Active ☐ Closed ☐ Unk. Gender: _____

Last OAMC Appts:	Virally Suppressed?	← If No, linked to CM?
1.	☐ Y ☐ N ☐ Unk.	
2.	☐ Y ☐ N ☐ Unk.	
3.	☐ Y ☐ N ☐ Unk.	
☐ No appts. during review period		

Last CMngmt. Contact:	Type (F2F/PC/Consult.) + short description)	Signed/Dated/Clear?
1.		
2.		
3.		
4.		
5.		

During the review period, was the client: ☐ New to care ☐ Lost to care ☐ Re-engaged in care ☐ NA
If yes.... was there documentation of coordination of care or contact attempts? ☐ Y ☐ N ☐ NA

Does the client have an active diagnosis of the following diagnoses? (Check ALL that apply)
☐ Alcohol abuse/dependence
☐ Other substance abuse/dependence: _____
☐ Depression
☐ Bipolar disorders
☐ Anxiety disorders
☐ Schizophrenia
☐ Other: _____

Was the client referred or already engaged with MH/SA services?
☐ N/A ☐ Yes ☐ No

Does the client have any co-morbidity?
☐ Opportunistic Infection
☐ Sexually Transmitted Infections (STIs) : _____
☐ Diabetes
☐ Cancer
☐ Hepatitis
☐ Hypertension
☐ Other: _____

Was the client reported to have any of the following conditions?
☐ Homelessness
☐ Pregnancy (or other pregnancy-related conditions)
☐ Recently released
☐ IPV

INSURANCE, BENEFITS, AND INCOME INFORMATION

Health Insurance: ☐ Uninsured ☐ Medicaid _____ ☐ Medicare_____ ☐ Commercial _____
☐ VA ☐ Other? _____

Spouse/partner:	Children:	Other Dependents:	TOTAL HOUSEHOLD SIZE 1 2 3 4 5 6 7 8 9 10 Unk
Client Income $:	Spouse Income $:	Other Income $:	TOTAL HOUSEHOLD INCOME $:

Did the client lose insurance or coverage during the review period? ☐ Y N ☐ Unk. ☐
If so, were they provided with information/education or assistance? ☐ Y N ☐ NA ☐

CASE MANAGEMENT SERVICES

What types of services were provided by a **Medical Case Manager** (MCM?)	What types of services were provided by a **Service Linkage Worker** (SLW?)	Was the client referred for **Clinical Case Management** services in the review period?
☐ **NA (Client not assisted by MCM)** ☐ Comprehensive assessment ☐ Service Plan ☐ Medication adherence counseling ☐ Coordination of medical care ☐ Transportation ☐ ADAP/medication assistance ☐ Eligibility ☐ Community resource/benefits brokerage ☐ Other _____ Did client meet criteria for MCM? Y ☐ N ☐ Unk. ☐	☐ **NA (Client not assisted by SLW)** ☐ Brief assessment ☐ SLW referred client to OAMC ☐ OAMC visit scheduled by SLW ☐ SLW accompanied client to OAMC ☐ SLW called client to remind about OAMC visit ☐ Client did not keep OAMC appt. and SLW contacted them ☐ ADAP/medication assistance ☐ Transportation voucher ☐ Eligibility Were any of the above services provided by an Outreach Worker? Y ☐ N ☐ Unk. ☐	☐ **No- not applicable** ☐ No- applicable, but no referral documented ☐ Yes- and there is evidence of coordination of services ☐ Yes- and there is no evidence of coordination of services ☐ Yes- but client refused services or is already engaged in treatment

Was the case discharged/closed for CM during the review period?		Y ☐	N ☐	NA ☐	Unk. ☐
If yes.....	Client met agency criteria for closure?	Y ☐	N ☐	NA ☐	Unk. ☐
	Client completed treatment program (CCM)	Y ☐	N ☐	NA ☐	Unk. ☐
	Date and reason noted?	Y ☐	N ☐	NA ☐	Unk. ☐
	Summary of services received?	Y ☐	N ☐	NA ☐	Unk. ☐
	Referrals noted?	Y ☐	N ☐	NA ☐	Unk. ☐
	Instructions given to client at discharge?	Y ☐	N ☐	NA ☐	Unk. ☐

ASSESSMENTS & SERVICE PLANS

		If no assessment or plan:		
Brief Assess. Date 1:	Brief Assess. Date 2:	☐ evidence of one just outside of review period	☐ reason documented	☐ enough info to complete
Comp. Assess. Date 1:	Comp. Assess. Date 2:	☐ evidence of one just outside of review period	☐ reason documented	☐ enough info to complete
Service Plan Date 1:	Service Plan Date 2:	☐ evidence of one just outside of review period	☐ reason documented	☐ enough info to complete

COMPLETED ASSESSMENTS

Domain	MOST RECENT ASSESSMENT TYPE (circle one) Comprehensive Brief					NEXT MOST RECENT ASSESSMENT TYPE (circle one) Comprehensive Brief				
	Assessed?	Need Identified?	Accounted for in Service Plan?	Accounted for in progress notes?	Follow-up (referral, action, etc.)	Assessed?	Need Identified?	Accounted for in Service Plan?	Accounted for in progress notes?	Follow-up (referral, action, etc.)
Medical/Clinical										
Vaccination										
Nutrition/Food Pantry										
Dental Care										
Vision Care										
Hearing Care										
Home Care Needs										
Basic Necessities/Life Skills										
Mental Health										
Substance/Alcohol Use										
Abuse History										
Housing/Living Situation										
Support System										
Child Care/Guardianship										
Insurance Benefits										
Transportation										
HIV-Related Legal										
Cultural/Linguistic										
Self-Efficacy										
HIV Education/Prevention										
Family Planning/Safer Sex										
Employment/Income										
General Education/Vocation										
Financial Assistance										
Medication Adherence										
Client Strengths										
Other										

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EHEALTH AND HIV (J SIMONI AND J STEKLER, SECTION EDITORS)

The Impact of COVID-19 on HIV Care Provided via Telemedicine—Past, Present, and Future

Jehan Z. Budak[1] · John D. Scott[1] · Shireesha Dhanireddy[1] · Brian R. Wood[1]

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Abstract

Purpose of Review This review summarizes HIV care delivered via telemedicine before and during the COVID-19 pandemic and highlights areas of study to inform optimal usage of telemedicine in HIV clinical practice in the future.

Recent Findings To address barriers to care created by the COVID-19 pandemic, regulatory agencies and payors waived longstanding restrictions, which enabled rapid expansion of telemedicine across the country. Preliminary data show that providers and persons with HIV (PWH) view telemedicine favorably. Some data suggest telemedicine has facilitated retention in care, but other studies have found increasing numbers of PWH lost to follow-up and worsened virologic suppression rates despite offering video and/or telephone visits.

Summary The COVID-19 pandemic has exacerbated gaps in the HIV care continuum. To help mitigate the impact, most clinics have adopted new virtual care options and are now evaluating usage, impact, and concerns. Further research into the effects of telemedicine on HIV care and continued work towards universal access are needed.

Keywords Telemedicine · HIV · COVID-19 · PrEP

Introduction

The coronavirus disease-2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has disrupted the world and impacted every stage of the HIV care continuum. Clinics have experienced interruptions to their usual care models [1], and some have already identified decreases in viral suppression rates, especially for individuals experiencing homelessness, despite stable retention-in-care and visit volumes for in-person and telephone visits [2]. Interruptions in care and decreased viral suppression rates also have also impacted HIV transmission [3]. For many persons with HIV (PWH), the clinic serves as a medical home, and the pandemic has created substantial barriers to accessing primary care and other multidisciplinary services while trying to maintain safe physical distancing.

To help overcome barriers to care that have been created or exacerbated by the COVID-19 public health emergency, clinics have near universally launched or expanded telehealth options and entered a new era of virtual, distance-based medical care. Telehealth, as defined by the United States (U.S.) Health Resources and Service Administration (HRSA), is "the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient, and professional health-related education, public health, and health administration" [4]. Telehealth can encompass distance-based provider-to-patient interactions, provider-to-provider modalities, store-and-forward communications, and mobile health applications [5]. The term telemedicine specifically refers to clinical care provided via video teleconferencing. Thus, in this review, we focus on synchronous provider-to-patient video visits, which we refer to as telemedicine.

Though telemedicine has long been technologically feasible, prior to the COVID-19 pandemic, regulatory and reimbursement barriers hindered implementation, and its use was limited to specific healthcare systems or unique situations and to research settings. When the COVID-19 pandemic reached the U.S., however, clinics across the nation needed to rapidly implement or expand telemedicine options as a way to deliver

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✉ Jehan Z. Budak
jehan@uw.edu

[1] Division of Allergy and Infectious Diseases, University of Washington, MS 359930, 325 9th Avenue, Seattle, WA 98104, USA

care while supporting stay-at-home and shelter-in-place precautions [6]. To facilitate this expansion, Congressional House Bill 6074 allowed the Department of Health and Human Services (DHHS) to temporarily waive certain telemedicine restrictions, and the Centers for Medicare & Medicaid Services (CMS) enacted several emergency waivers to facilitate expansion of telemedicine services [7]. Examples of telemedicine restrictions waived include regulations that previously required patients to live in designated rural or medically underserved areas, that only allowed certain providers to bill for telemedicine visits, and that prohibited patients from joining video visits from home [8]. In addition, private payors amended restrictions around reimbursement, cost-sharing, prescription refill limits, and other policies. These regulatory and reimbursement changes allowed for a brisk and dramatic propagation of telemedicine services. Exemplifying the significant shift, in February 2020, 0.1% of Medicare visits were conducted electronically, versus 43.5% in April 2020 [9].

Although some clinics and healthcare systems were well prepared for the shift to telemedicine (i.e., with technologic platforms and protocols already in place), many were not. Most are now in the process of troubleshooting, evaluating barriers from the patient and provider perspective, devising solutions, and optimizing usage. Furthermore, the landscape once the current pandemic ends is difficult to predict; there are advantages to maintaining telemedicine options but how this will be balanced with the benefits of in-person visits and how the current regulatory waivers will change remain unclear. In this review, we (1) summarize the use of telemedicine for HIV treatment or prevention prior to the COVID-19 pandemic, (2) describe implementation strategies incorporated by clinics and health systems to sustain HIV and pre-exposure prophylaxis (PrEP) care during the COVID-19 pandemic, and (3) discuss future research questions and policy needs that will be crucial to address to inform future telemedicine usage.

Telemedicine for HIV Care Before COVID-19

Prior to the COVID-19 pandemic, PWH and their providers expressed interest in telemedicine. For example, a survey of 371 PWH in the Houston area found that 57% of respondents were, "more likely to use telehealth for their HIV care, if available, as compared to one-on-one in-person care," and 37% answered they would use telehealth frequently or always as an alternative to clinic visits [10]. Similarly, in a survey of physicians who cared for PWH, 85% believed telemedicine could improve access and timeliness to care [11].

While PWH and HIV care providers were interested in telemedicine, before the COVID-19 public health emergency, data for the effects of telemedicine on clinical outcomes in HIV care were limited. Importantly, most models for telemedicine required a patient to travel to a clinic or other setting in order to connect to their visits, as regulations prevented them from connecting from home. Thus, comparisons to current models of telemedicine are difficult. That said, findings were generally favorable and suggested many potential benefits of telemedicine. For example, in a small study of PWH in a rural setting within a Veterans Affairs (VA) healthcare system, thirty of 32 eligible patients chose to participate in a video conferencing option [12]. Participation in telemedicine decreased travel time, led to patient satisfaction, and improved rates of flu vaccination and screening for syphilis, depression, tobacco use, and alcohol use. No statistically significant difference in retention in care or virologic suppression was observed between the groups [12]. Then, Ohl and colleagues performed a large, cluster-randomized study at clinics across three VA networks, where 1670 PWH were offered telehealth visits [13]. Video conferencing was used uniformly, though other telehealth modalities were included and varied by site. Patients were given the option to either travel to a nearby primary care clinic to use telemedicine to connect with their HIV provider or to travel to see their HIV provider in person. Only 120 (13%) PWH opted into the telemedicine option. The authors postulate that uptake was low because patients were already accustomed to traveling to their HIV clinic and that relatively little travel time would be saved with the telemedicine strategy (connecting from home was not an option due to the regulatory environment at the time) [13]. For those who used telemedicine, as compared to those who did not, investigators observed an increase in the number of HIV clinic visits and more frequent viral load testing, though neither the availability of telemedicine nor its usage was associated with improved viral suppression [13]. Lastly, in a retrospective chart review of PWH in rural Georgia receiving HIV care, of 385 cases reviewed (200 in-person encounters through one clinic and 185 telemedicine encounters through another), there was no statistically significant difference in mean viral load or in rates of year-round viral control between those who had in-person versus telemedicine visits [14].

Prior to the COVID-19 pandemic, some experience and data had accumulated for use of telemedicine to support HIV care in correctional settings. In a retrospective cohort study of 687 PWH in a corrections system, use of telemedicine to access HIV subspecialty care was associated with greater virologic suppression and higher CD4 T-cell counts [15]. The use of video conferencing to increase linkage to care post-release has also been studied, though, in an analysis of 144 PWH who used video conferencing with case managers in community-based organizations, telemedicine usage did not lead to a statistically significant difference in linkage rates [16]. Despite this, the authors note that telemedicine was positively received by both patients and case managers [16].

Heterogeneity of study design and telemedicine implementation logistics makes comparison between the above studies difficult. In HIV primary care settings, outcomes, including

virologic suppression, were similar between telemedicine and in-person visits, and in some studies, telemedicine lowered barriers to care, especially barriers related to distance and travel needs. Consistent across the studies was the finding that PWH and their providers had positive attitudes toward telemedicine and were interested in its growth as an option to access care. Many expected that the numbers of individuals utilizing telemedicine in HIV and infectious diseases (ID) would continue to grow [17]. What was unanticipated, however, was the dramatic proliferation of telemedicine service implementation across the country, precipitated by the COVID-19 public health emergency.

Telemedicine for HIV Ambulatory Care During the COVID-19 Pandemic

On March 23, 2020, the DHHS published interim guidance for COVID-19 and PWH and suggested providers prescribe 90-day supplies of antiretroviral medications, instead of 30-day supplies, change to mail-order medications instead of pick-ups, and, when possible, extend the interval and frequency with which PWH have clinic and laboratory visits [18]. In addition, the DHHS stated that video or telephone visits could replace in-person encounters for routine or non-urgent care [18].

It is clear that since the pandemic started and the regulatory and reimbursement landscape changed, telemedicine access has increased for PWH [19]. For example, Mayer et al. describe outcomes for PWH at a Boston community health center. In the first two months of 2020, their clinic had a mean of 626 in-person visits and zero telemedicine visits [20]. In March and April 2020, however, the number of in-person visits dropped to 370 and 360, respectively, while the number of telemedicine visits increased to 263 and 751 visits, respectively [20]. When telemedicine and in-person visits were combined, the mean number of visits per month by PWH was higher between March and September 2020 as compared to the same seven-month period in 2019 [20]. Despite an initial decrease in the mean number of plasma HIV RNA tests performed, monthly rates of virologic suppression at this clinic were similar between 2019 and 2020. Thus, though the number of in-person visits decreased, the authors concluded that engagement in care, based on viral suppression rates and the total number of visits, remained constant during the COVID-19 pandemic [20]. In contrast, investigators at a Midwestern academic HIV clinic serving approximately 1100 PWH, who shared operational details and quality improvement strategies from their transition to telemedicine, also assessed viral suppression and retention in care data [21]. From February to August 2020, viral suppression rates did not change, but the number of patients lost to follow-up (which they defined as patients not seen for one year or more) increased from 34 to 59 [21].

Rogers et al. described a rapid shift to telemedicine for PWH at a newly opened LGBTQ+ clinic in Rhode Island. Anecdotally, providers had positive experiences with telemedicine and appreciated, "the opportunity to care for patients who may have more difficulty making it to in-person visits" and "the opportunity to observe patients in their homes to provide more context for their social circumstances" [22]. Patient feedback was elicited through a patient satisfaction survey, in which approximately 25% of respondents reported interest in receiving care via telemedicine, though patients also reported concerns about privacy, data breaches, billing, and insurance challenges [22]. These investigators do not report viral suppression rates, but received positive feedback from patients and providers about their experience with video visits.

In summary, most patients and providers reported positive attitudes toward telemedicine during the COVID-19 pandemic, suggesting the modality is likely to remain a part of HIV care in the future. While some studies found stable rates of virologic suppression and engagement in care [20, 21], others noted increased numbers of PWH lost to follow-up [21]. The explanation for these contrasting results may be due to differences in study design, telemedicine protocols and policies, or proportion of patients with the means to access telemedicine visits. Importantly, connecting to a visit via telemedicine does not supplant the wrap-around services often needed to help an individual achieve virologic suppression [2, 23]. Thus, given that it is difficult to generalize from these studies alone and that communication with a provider is one of many elements necessary for patients to succeed with HIV treatment, more data regarding virologic suppression and retention in care during this new telemedicine era are required.

Telemedicine for Pre-Exposure Prophylaxis Care During the COVID-19 Pandemic

The pandemic accelerated the expansion of telemedicine for pre-exposure prophylaxis (PrEP) care as well. Though prior innovations in the use of telemedicine to overcome barriers to PrEP dissemination and adherence were limited to small geographic pockets or unique settings [5, 24, 25], guidance during the public health emergency encouraged telemedicine usage to deliver PrEP care [26]. Most providers have modified their PrEP practice during this time, largely through incorporation of telehealth modalities [27]. In addition, approximately 54% noticed that their ability to test for HIV or STIs dropped [27]. This decrease in testing was mirrored by patient experiences. In an online survey of men who have sex with men in the Southern U.S. who use PrEP, during the pandemic, 47% did not receive an STI test and 35% did not receive an HIV test [28] and a Boston clinic observed that the number of HIV tests decreased by 85.1% [29]. Data from the Boston community

health center specializing in sexual healthcare showed that despite a rapid transition to telemedicine, COVID-19 was still associated with disruptions in PrEP care [29]. Specifically, between January and April 2020, they found that PrEP refill lapses increased by 191% and that new PrEP starts decreased by 72.1% [29]. Physical distancing and stay-at-home orders may have contributed, as a survey study found that of individuals who stopped PrEP voluntarily, 85% stopped due to low perceived risk [27]. Though PrEP visits and prescriptions plummeted during this time, many may have stopped PrEP appropriately in the context of strict physical distancing. As the need for PrEP can fluctuate, we do not yet know whether the individuals who discontinued PrEP have re-started or re-engaged in care. In addition, we need more information about the individuals who stopped PrEP due to access barriers so as to better understand how telemedicine could help relieve such barriers.

Unanswered Questions and Future Directions of Telemedicine for HIV and PrEP Care

Remote visits have several advantages beyond promoting physical distancing, including convenience; decreased travel time, expenses, or time away from work; helping individuals who fear stigma when attending clinic visits; and, importantly, helping individuals stay safe and healthy, particularly if they have risk factors for serious COVID-19 [8, 30]. Despite this, several concerns about the use of telemedicine exist, including quality of care, privacy in the home or other living situation, reimbursement, cost, medicolegal risks, increased administrative burden, and lack of institutional support [31–33]. Also, both PWH and their providers worry about decreased personal connections in their relationship [11].

One of the most pressing and significant concerns about telemedicine regards the socioeconomic disparities that prevent some individuals from accessing, and thus benefitting equally, from telemedicine. This "digital divide" is defined as the unequal access or ability to engage in care using technological means [8]. For example, female, older, lower income, and non-English-speaking patients are more likely to complete a telephone visit instead of a video visit, and non-English proficiency has been associated with a more than 50% decrease in the use of either video or telephone visits [8, 34]. Some individuals have difficulty with video visits, often due to absence of broadband connectivity, inexperience with the technical hardware or software required, or lack of a private space in which to join a visit. Many such individuals thus rely on telephone visits to stay engaged with care; as such, telephone visits have become a crucial safety net for many patients to stay connected. The digital divide existed prior to the pandemic, and some efforts to mitigate it have been previously described, such as through individualized coaches for PWH with low health literacy to help increase their capacity to utilize the electronic health record [35]. Despite such efforts, the digital divide persists and has become more apparent due to the pandemic. A Policy Paper from the Infectious Diseases Society of America (IDSA) and HIV Medical Association (HIVMA) outlines four requirements for successful video visits (technology, technical literacy, broadband connectivity, and personal privacy), lists potential interventions to mitigate the impact of social determinants of health on telemedicine access, and calls for further research to better understand who is and who is not accessing and benefitting from telemedicine in ID and HIV clinical practice [8].

With the arrival of multiple COVID-19 vaccines, we need to start planning for the use of telemedicine after the COVID-19 pandemic, both for persons with and without HIV. Many questions about the optimal usage and benefits of telemedicine and the risks of relying on telemedicine remain. Furthermore, since many of the telehealth regulatory waivers are temporary, what will the landscape of telehealth look like in a post-pandemic environment? We believe telemedicine should and will remain an option after the COVID-19 pandemic and argue that regulations to support telemedicine should be made permanent. The ability to offer visits via distance and to individualize decisions about whether a person should be seen in-person or by video or telephone augments the ability to help every individual access the care they need. Payment parity for telemedicine visits is crucial and should be maintained, and payment parity for telephone visits is also necessary because those individuals who cannot access distance-based care by video often rely on phone visits to stay connected to care. Additional questions for future study that may facilitate optimal integration of telemedicine into medical care, in general and for care specifically for PWH or persons at risk for HIV, are suggested in Table 1.

Conclusions

The COVID-19 pandemic has revolutionized the practice of ambulatory medicine. We have entered an era in which we need to build telemedicine models that empower PWH and improve access to care [30, 36]. In fact, the pandemic has accelerated differentiated care delivery in the U.S. [37, 38]. Differentiated service delivery (DSD), a care model that originated in sub-Saharan Africa, is care that is tailored to the local context and to patients' clinical status [38]. Thus, telemedicine is a form of differentiated care delivery, and we should advocate for its continued presence and expansion in the care of PWH. This advocacy should include support for the recommendations regarding the use of telehealth to strengthen the Ending the HIV Epidemic Initiative [39], implementation of

Table 1 Potential questions and areas of study to inform future usage of telemedicine in HIV clinical care

Questions	Comments and examples
Patient-focused factors	
What does the patient prefer?	• Clinics should tailor the implementation of telehealth to their specific patient population, organizational structure, and location. • Which patients prefer video visits, telephone visits, or in-person visits?
Is the quality of care when primarily using telemedicine equivalent to traditional in-person care? How can the quality of care be ensured and optimized?	• More data regarding outcomes, including HIV-specific outcomes, such as viral suppression rates, and primary care outcomes, such as vaccination or cancer screening rates, are needed. • What is missed with a video visit? • What is the best way to ensure laboratory work or STI testing is completed? If laboratory work is ordered during a video visit, how can we ensure the patient is not billed twice (i.e., with a facility fee)?
Which clinical indications for a visit should absolutely be in-person?	• Mgbako et al. suggest in-person visits be prioritized for individuals newly diagnosed with HIV, new to the clinic, who are non-English-speaking, with limited access to technology, or with low health or technology literacy. • Patients with symptoms requiring a hands-on physical exam should be seen in-person. • Is there a best balance between frequency of video versus in-person visits for routine care of an asymptomatic individual?
Which patients are able to successfully engage in care via telemedicine? How do we prevent the new telemedicine era from excluding certain individuals?	• Which barriers are overcome by telemedicine, such as transportation or stigma, and which barriers remain or are exacerbated? • Who is not engaging in telemedicine, and why not? • How can we ensure all have access to a device and broadband connection and that those with limited English proficiency, vision, hearing, or cognitive impairment are not excluded?
Provider-related factors	
Do providers feel comfortable performing video visits?	• What resources will empower providers to feel more confident with telemedicine visits?
What are the best practices for telemedicine? How do we teach this and incorporate it into medical school and training programs?	• How can training regarding telemedicine best practices be incorporated into medical school and post-graduate training so that providers entering the workforce are comfortable with this modality?
Patient-provider interactions	
Are patient-provider relationships more impersonal with telemedicine?	• How do patients feel about the care they receive via video-visit? • Are patients more or less likely to stay with the same provider or clinic, and does the level of trust in their providers change?
Do video visits increase provider implicit bias?	• Are implicit biases elicited by visualizing a patient's living environment? • Are some individuals being offered or not offered video visits simply because of demographic factors, like age or language?
Telemedicine logistics and clinic operations	
What is the added burden on clinics as a whole? How can clinics maximize efficiency while ensuring universal access to high-quality care via video visits?	• How can clinic flow (i.e., templating, check-in and check-out processes, space, and resource allocation) be streamlined for telemedicine? • How can we maximize the patient experience while minimizing administrative and operational requirements?
Can wrap-around services for HIV be successfully delivered through telemedicine?	• How do we bring team-based care, central to Ryan White clinics, to the telemedicine platform?

the points suggested for Advancing Digital Health Equity, as outlined by the IDSA and HIVMA [8, 40], and adherence to recommendations for telemedicine for the population as a whole [41, 42]. In addition, some have proposed that telemedicine become a Ryan White HIV/AIDS Program surrogate measure of retention in care [40, 43]. Lastly, given the structure of Ryan White clinics, we need to determine how best to provide wrap-around services and team-based care through telemedicine.

Telemedicine is at a critical juncture. It has been utilized for many years and will likely continue into the future, yet the way in which it will be utilized, how much it will be incorporated into routine clinical practice, and the degree to which it will be accepted by patients and providers in a post-pandemic period is yet to be determined. Hence, we have summarized what is currently known about the use of telemedicine in PWH and how its use for PWH has grown exponentially in the midst of the pandemic and have highlighted questions and concerns which need to be addressed. Telemedicine provides an exciting opportunity to tailor care to each individual patient, to avoid traditional "one-size-fits-all" ambulatory care models, and to move toward delivering more innovative and differentiated care so that we may ultimately end the HIV epidemic.

Declarations

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

Conflict of Interest John Scott reports personal fees from Gilead Sciences and Premera Blue Cross. None of the other authors has any conflicts to disclose. Jehan Budak, Shireesha Dhanireddy, and Brian Wood declare that they have no conflict of interest.

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- •• Of major importance

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Immediate Initiation of Antiretroviral Therapy in the Outpatient Clinic

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Contributors: Susa Coffey, MD
Oliver Bacon, MD

In 2013, the Ward 86 HIV Clinic at the University of California, San Francisco (UCSF) at San Francisco General Hospital (SFGH) became the first clinic in the United States to provide immediate antiretroviral therapy (ART) upon HIV diagnosis. Our program, called RAPID (Rapid ART Program for Individuals with an HIV Diagnosis), aims to initiate ART as close to the time of HIV diagnosis as possible, ideally on the same day, with the goal of mitigating impediments to linkage to care, helping patients maintain treatment after initiation, and enhancing the health of highly vulnerable individuals and communities with HIV. This treatment strategy also is known as "rapid start," "same-day ART," or "treatment upon diagnosis." Other potential benefits of initiating ART immediately upon HIV diagnosis include reducing the risk of onward transmission of HIV and, among persons with acute HIV infection, reducing the size of the latent HIV reservoir.

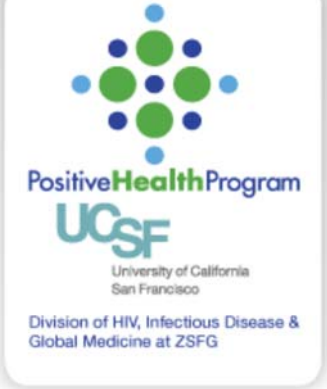
Analysis of the pilot phase of RAPID during 2013-14 showed participants had earlier linkage to care, earlier start of ART, and a shorter time to HIV RNA suppression compared with historical controls.(1) An analysis of San Francisco citywide data conducted after rapid initiation of ART was promoted as standard practice in the city showed the median time from HIV diagnosis to first virologic suppression was shortened by more than 50% in 2016 compared with 2013 (from 134 to 61 days).(2,3) Subsequent demonstration projects from clinics in New Orleans, Los Angeles, and Atlanta similarly found that implementation of immediate ART programs also led to earlier linkage to care and shorter time to virologic suppression than seen in historical controls.(4,5) A more recent analysis of 225 patients referred to our Ward 86 RAPID program from 2013-17 revealed 97% of them were started on immediate ART, indicating high acceptability.(6) Of note, 51.4% of these participants had an active substance use disorder, 48.1% had a mental health diagnosis, and 30.6% were unstably housed, which is reflective of the public health population we serve. Yet, by 1 year after intake, 95.8% had achieved viral suppression (HIV viral load <200 copies/mL), and 92.1% were suppressed at the time of their last recorded viral load (at a median 1.09 [range 0-3.92] years).

Current guidelines from the U.S. Department of Health and Human Services and the International Antiviral Society--USA endorse ART initiation at the time of diagnosis or as soon as possible afterwards.(7, 8)

Implementing Immediate ART in the Outpatient Clinic

In our experience, success of rapid ART programs is greatly enhanced by coordinated activity among HIV testing sites, immediate-ART clinical care site(s), and, ideally, involvement of HIV care navigators and public health tracking systems. Within the HIV clinic itself, optimal implementation of a rapid ART program includes the following elements:

- Efficient and reliable identification of all persons with new HIV diagnosis (for example, referral from testing sites via a single point of contact such as a dedicated pager or specific staff person).



About This Series

This series offers clinical practice recommendations for management of HIV-related conditions from the Ward 86 staff of the Positive Health Program at San Francisco General Hospital. Learn more.

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- Activation of a "rapid" multidisciplinary team (social work, eligibility/insurance specialist, clinician) that can mobilize quickly to see the patient on a same-day basis.
- Capacity to provide follow-up care within 1 week.

Appropriate patients to offer immediate ART include:

- Individuals with confirmed new diagnoses of HIV infection.
- Persons with suspected acute HIV infection whose HIV diagnosis may not yet be confirmed (eg, the HIV antigen or antibody test results may be negative at the time of evaluation).
- Persons with positive results of rapid HIV antibody tests, before confirmatory test results are available, if the pretest probability of HIV infection is high (after counseling, immediate ART is offered with the understanding that, if confirmatory test results are negative, the patient would stop ART and start pre-exposure antiretroviral prophylaxis, if appropriate).
- Chronically infected patients who have never received ART.
- Chronically infected patients who return to care after being out of care and off ART, if they have a known wild-type virus or their viral resistance pattern is predictable (these persons may require individually-tailored regimens).

Immediate ART should *not* be offered to:

- Patients with an untreated opportunistic infection (OI) in which a short period of treatment for the OI is recommended before initiation of ART in order to reduce risk of a dangerous immune reconstitution inflammatory syndrome (eg, those with cryptococcal meningitis, tuberculosis meningitis, another central nervous system OI with inflammation, or cytomegalovirus retinitis).
- Patients who are unwilling or unready to start ART. Such individuals should be followed closely and offered ART at subsequent visits. In our experience, patients who are not ready at the first visit may be ready as soon as several days later.

The Immediate ART Clinic Intake Visit

The immediate-ART intake appointment should focus on the goals of providing HIV education, emotional support, and counseling, insurance enrollment or optimization, obtaining specimens for baseline laboratory tests, and initiation of ART. In our setting, a specialized multidisciplinary team comprised of a social worker, a nurse, and a clinician meet with the patient and conduct the intake, either together or sequentially, usually for a duration of 2-3 hours.

All clinicians provide the patient with emotional support and reassurance around the diagnosis of HIV and education about HIV infection. The social worker assists with insurance enrollment or optimization for both clinical care and prescription medications and addresses any immediate needs for stabilization. The clinician takes the patient's history and performs an assessment with the following goals:

- Obtaining sufficient information from the history to determine whether immediate ART is indicated, whether the patient is willing to start ART, and what medications to use
- Beginning education about HIV, ART (eg, possible benefits of early ART, adherence), and preventing transmission to others
- Engaging the patient in committing to return to clinic for follow-up appointments

Our recommended laboratory tests for the intake visit are listed in Table 1, and specific ART regimens we recommend are listed in Table 2. We have purchased starter medication packs, which contain a 3- to 5-day supply of the selected ART regimen, to give patients at the intake visit when necessary. Starter packs may not be necessary if immediate access to antiretroviral medication can be assured (eg, via an in-clinic pharmacy or good coordination with an off-site specialty pharmacy that is skilled in serving patients with the AIDS Drug Assistance Program [ADAP] or other public assistance insurance programs).

Follow-Up Visits

Patients who are started on ART at the first clinic visit often need additional education and support in the days and weeks that follow. Because they recently have been diagnosed with HIV and started on ART with little or no advance preparation upon diagnosis, they will need additional HIV-related education, reinforcement regarding adherence, counseling about preventing HIV transmission, and information and encouragement about living healthy lives with HIV.

We recommend scheduling a phone check-in with a social worker, nurse, or clinician 2-3 days after the intake appointment, and scheduling a clinic follow-up appointment at 1-2 weeks. The timing of the

follow-up visit will depend on the needs of the patient, but in general, it should take place no later than 1 month after the patient is started on ART. The frequency of subsequent visits should be determined by the primary care provider in consultation with the patient.

At the follow-up appointment, clinicians should review baseline laboratory results with the patient, evaluate ART adherence, screen for side effects, and provide further counseling and education. Once the genotype result is available (from the baseline lab draw), the clinician can decide whether a change in the ART regimen is indicated, though unnecessary changes generally should be avoided.

Table 1. Recommended Laboratory Tests at Immediate ART Intake Visit

• Confirmatory HIV testing (if needed) • HIV viral load • CD4 cell count • HIV genotype, including integrase genotype • HLA-B*5701 • Metabolic panel (creatinine, electrolytes, glucose, liver function tests)	• Hepatitis A IgG • Hepatitis B sAb, cAb, Ag • HCV IgG • STD testing: serum RPR or VDRL, chlamydia and gonorrhea NAAT tests (urine, pharynx, rectum, depending on sites of sexual exposure) • Pregnancy test (if indicated) • Consider: lipids, G6PD, toxoplasma IgG

Table 2. Recommended Immediate ART Regimens

Since ART is initiated during the initial clinic visit, before results of baseline testing (including HIV RNA, CD4 count, genotype, HLA-B*5701, and creatinine) are available, we recommend prescribing regimens that will be potent and effective in the setting of high viral load and/or transmitted viral resistance. Once results of the HIV genotype are available, the regimen can be modified, if indicated. The ART regimens should also be simple to adhere to and confer minimal risk of adverse effects.

Preferred regimens (based on clinical trial data and clinical experience)	• Bictegravir/tenofovir alafenamide/emtricitabine (Biktarvy) • Dolutegravir* (Tivicay) + tenofovir alafenamide/emtricitabine (Descovy) or tenofovir disoproxil fumarate/ emtricitabine (Truvada) or tenofovir disoproxil fumarate/lamivudine
Alternative regimens (based on potential for more adverse effects or higher costs)	• Darunavir (Prezista)/cobicistat/tenofovir alafenamide/emtricitabine (Symtuza), or • Darunavir + ritonavir + tenofovir alafenamide/emtricitabine (Descovy) or tenofovir disoproxil fumarate/ emtricitabine (Truvada) or tenofovir disoproxil fumarate/lamivudine

* Dolutegravir has been associated with a small increased risk of neural tube defects in infants born to women who were taking dolutegravir at the time of conception. No data are available on the safety of bictegravir for fetuses exposed at time of conception or early in pregnancy. For persons of childbearing age who may become pregnant while taking dolutegravir (or bictegravir) (eg, cisgender women who have male sex partners and are not using effective contraception), we recommend that providers discuss possible risks and benefits of dolutegravir and alternative ARVs, and select ARVs through shared decision making.

During Pregnancy:

Certain ARVs have not been studied or are not recommended during pregnancy. Thus, rapid-ART regimens for a someone who is pregnant or who may become pregnant must be selected individually, after careful discussion with the patient.(9)

For patients who had been taking antiretroviral prophylaxis as pre- or postexposure prophylaxis (PrEP or PEP) at the time of HIV infection or since becoming infected with HIV:

- Take a careful history to determine the last time the patient took PrEP or PEP medications.
- If we have concern that resistance to the antiretrovirals may have developed, we generally start

a reinforced ART regimen consisting of an integrase inhibitor (dolutegravir or bictegravir) + boosted darunavir + a tenofovir/emtricitabine or tenofovir/lamivudine formulation while awaiting the results of the genotype assay.

Antiretroviral drugs to AVOID for immediate ART:

- Avoid 2-drug antiretroviral regimens (eg, dolutegravir + lamivudine [Dovato] or dolutegravir + rilpivirine [Juluca]): high risk of virologic failure in patients with transmitted resistance. Two-drug regimens have not been studied for use in immediate ART.
- Avoid nonnucleoside reverse transcriptase inhibitors (NNRTIs): high risk of transmitted NNRTI resistance.
- Avoid abacavir (including coformulations that include abacavir): risk of hypersensitivity reaction if positive for HLA-B*5701.

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The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a U.S. Public Health Setting

Christopher D. Pilcher, MD[1,*], **Clarissa Ospina-Norvell, FN-P**[1], **Aditi Dasgupta, BS**[2], **Diane Jones, RN**[1], **Wendy Hartogensis, PhD**[1], **Sandra Torres, MSW**[1], **Fabiola Calderon, MSW**[1], **Erin Demicco, MPH**[1], **Elvin Geng, MD**[1], **Monica Gandhi, MD**[1], **Diane V. Havlir, MD**[1], and **Hiroyu Hatano, MD**[1]

[1]Division of HIV, Infectious Diseases and Global Medicine, Department of Medicine, University of California, San Francisco, California

[2]Tulane University School of Medicine, New Orleans, Louisiana

Abstract

Background—ART is typically begun weeks after HIV diagnosis. We assessed the acceptability, feasibility, safety and efficacy of initiating ART on the same day as diagnosis.

Methods—We studied a clinic-based cohort consisting of consecutive patients who were referred with new HIV diagnosis between June 2013 and December 2014. A subset of patients with acute or recent infection (<6 months) or CD4<200 were managed according to a “RAPID” care initiation protocol. An intensive, same-day appointment included social needs assessment; medical provider evaluation; and a first ART dose offered after labs were drawn. Patient acceptance of ART, drug toxicities, drug resistance and time to viral suppression outcomes were compared between RAPID participants and contemporaneous patients (who were not offered the program), as well as with an historical cohort.

Results—Among 86 patients, 39 were eligible and managed on the RAPID protocol. 37 (94.9%) of 39 in RAPID began ART within 24 hours. Minor toxicity with the initial regimen occurred in two (5.1%) of intervention patients versus none in the non-intervention group. Loss to follow-up was similar in intervention (10.3%) and non-intervention patients (14.9%) during the study. Time to virologic suppression (<200 copies HIV RNA/mL) was significantly faster (median 1.8 months) among intervention-managed patients when compared with patients treated in the same clinic under prior recommendations for universal ART (4.3 months; p=0.0001).

[*]Corresponding author address: Christopher D. Pilcher, MD Box 0874 San Francisco General Hospital Ward 84, 995 Potrero Avenue, San Francisco, CA 94110-0874, cpilcher@php.ucsf.edu.

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The authors declare no conflicts.

Conclusions—Treatment for HIV infection can be started on the day of diagnosis without impacting the safety or acceptability of ART. Same-day ART may shorten the time to virologic suppression.

INTRODUCTION

Early initiation of antiretroviral therapy (ART) reduces morbidity and mortality for patients with HIV infection [1–4], and reduces the potential for HIV transmission by suppressing viral replication [5]. Since 2010, guidelines from the San Francisco General Hospital (SFGH) HIV Clinic ("Ward 86") have accordingly recommended that ART be offered to all patients with HIV infection, regardless of CD4 cell count [6], a practice endorsed nationally in 2012 and worldwide in 2015. Supported by programs promoting linkage to care [7], this "universal ART" approach has been associated with reduction in the time from new diagnosis to virologic suppression in San Francisco [8].

However, structural barriers, patient attitudes and provider attitudes may impede the rapid initiation of HIV treatment. For example, HIV testing often occurs at a site different from that where treatment is initiated, which may result in weeks elapsing before a patient is able to link to HIV care. Additional steps are often required to secure health insurance benefits that will pay for ART, and to schedule and keep appointments with a new primary medical provider able to prescribe it.

Even when HIV care can be initiated in a clinic, other aspects of care are typically prioritized over ART at initial visits. Preparatory laboratory results (which usually include HIV genotyping, hepatitis serologies, etc.) can take weeks to return. In the traditional series of early events involved in linkage-to-care and ART initiation (Figure 1), labs may be drawn at initial visits but other aspects of care such as post-test counseling and education; management of housing and substance abuse problems are prioritized and ART initiation is deferred. In some circumstances, ART may be deferred until patients have "proved themselves ready" to adhere to ART by attending multiple clinic visits.

In 2013, the SFGH HIV clinic launched a clinical health systems intervention entitled RAPID (Rapid ART Program for Individuals with an HIV Diagnosis). This intervention was designed to facilitate ART initiation for patients with new HIV diagnoses, by immediately addressing structural barriers to dispensing same-day treatment. Under the RAPID care model (Figure 1), ART is initiated as soon as possible after HIV status is disclosed and ideally on the day patients are first referred for care—even as other aspects of linkage and engagement are ongoing. In this paper, we evaluated the feasibility, acceptability, safety and efficacy of a health systems intervention to promote same-day, observed ART initiation for HIV infection in a public health outpatient clinic setting.

METHODS

Study design

A clinic-based cohort study measured outcomes among individuals referred to care with a new diagnosis of HIV infection. The primary analysis compared outcomes among patients

who were initially managed according to the RAPID intervention protocol with those managed according to the clinic standard of care over the same time period. A second, pre- and post-intervention analysis compared outcomes in the intervention cohort with outcomes in a retrospective cohort of patients referred in prior years. This retrospective cohort included groups treated in both CD4-guided and universal ART treatment eras. All data were collected by review of electronic medical records. The evaluation was approved by the UCSF Committee on Human Subjects Research (UCSF CHR 12-10141).

San Francisco ART initiation guidelines

San Francisco's "universal ART" era was launched in January 2010 with SFGH HIV clinic and San Francisco Department of Public Health guidelines recommending that ART be offered immediately by primary care providers to all HIV-infected patients [6,9]. Previously, from 2006 through 2009, "CD4-guided" ART was recommended for patients with CD4+ T-cell counts <500 cells/mm^3.

Existing systems for referral and linkage at SFGH

The SFGH HIV Clinic provides outpatient continuity care to approximately 2800 HIV-infected patients. All residents of the County of San Francisco who do not have private health insurance are eligible for HIV care at this clinic. Referrals of new HIV cases come from public testing sites, off-campus clinics around San Francisco, and other outpatient and inpatient wards on the SFGH campus. Since 2002, all patients referred for initial HIV care at the clinic receive support from a multidisciplinary team of social workers, nurses and physicians providing comprehensive client services beginning with their first intake visit (as illustrated in Figure 1). In its standard of care approach, the SFGH HIV clinic team addresses medical (symptoms), social (housing, insurance, food access, immigration status) and psychological (counseling, mental health, substance use) concerns. This approach has been associated previously with excellent rates of linkage to care [7].

Intervention design

According to the novel RAPID care model (illustrated in Figure 1), ART should be initiated as soon as possible after a new diagnosis, preferably on the day of diagnosis, rather than deferred until patients are engaged in primary care. There was no active recruitment. The intervention involved no new procedures at HIV testing sites and no specific coordination with public health investigations. At our clinic, the RAPID program deployed the following intervention components to achieve its aim: 1) *Same-day access to an HIV provider*: patients were provided an appointment with an on-call HIV specialty physician or nurse practitioner on the day of diagnosis. Taxi vouchers were available for immediate transportation from the testing site to the clinic. 2) *Same-day medical visit outline*: During a same-day visit,lasting 3–4 hours, the prescribing provider provided education regarding HIV infection, risk reduction and sexual health, and benefits of ART with the patient. Possible contraindications to ART were assessed and the patient was given the option to decline treatment. Baseline laboratory tests (CD4 cell count and HIV RNA level, renal and liver function tests, hepatitis serologies, HLA B5701 testing, HIV resistance genotyping) were ordered but not typically available prior to ART start. 3) *Accelerated insurance approval process* Pre-existing, available protocols for emergency drug assistance in San Francisco were immediately

activated and follow-up of applications prioritized. 4) *Pre-approved regimens*: ART regimens that could be used without the results of genotyping or lab testing had been pre-approved by a local expert committee accounting for patterns of transmitted drug resistance and drug toxicity (e.g., dolutegravir and tenofovir disoproxil plus emtricitabine was approved and commonly used due to low prevalence of transmitted resistane to tenofovir and dolutegravir in SF). 5) *5-day starter packs*: Starter packs for each pre-approved regimen were available if needed for the participant to initiate ART while insurance benefits were being arranged (if benefits were in place, multiple dose starter packs were not necessarily provided). 6) *Observed administration of a first dose:* Patients accepting ART were offered the first dose in the clinic, with the provider in the room for support. 7) *Telephone follow-up:* RAPID nurses contacted patients within the first 7days to review lab results, inquire about adherence, pharmacy/prescription issues, and possible side effects. The timing of initial follow-up was guided by provider concern, and varied from 1–7 days.

Inclusion of new clinic patients in the intervention program

Between July 2013 and January 2014, RAPID was targeted to patients known at the time of referral as having *acute or recent HIV infection*, defined by having an HIV negative test within 6 months of referral. In January 2014, following initial demonstration of program feasibility, eligibility was expanded to *also include newly diagnosed individuals who had a CD4+ T-cell count <200/mm^3, active opportunistic infection, or an HIV seronegative sexual partner.* Importantly, the details of a patient's HIV testing history, symptoms and CD4 cell count were often not known at the time of referral. This resulted in several potentially eligible patients not receiving the intervention.

Intervention program participants and comparison groups included in analyses

We conducted two main comparative analyses to assess intervention impact: an intervention vs. no intervention analysis (looking at the same time period) and a pre- and post-intervention analysis (assessing change across multiple time periods). The first analysis considered all consecutive patients with new HIV infection who were referred to the clinic for care during the intervention period from July 2013 until December 31, 2014, and were either managed via the RAPID intervention program or not. The second (pre- and post-intervention) comparison also included data from an historical cohort of similar size who had been referred to SFGH in the pre-RAPID program period between 2006 and 2013. The historical cohort was selected using blocks of randomly assigned patient identification numbers from relevant periods. For all patient groups studied, analyses were limited to adult patients (≥18 years of age) initiating first outpatient HIV care at SFGH after a new diagnosis. Data from patients diagnosed for more than two years, patients transferring HIV care or already on ART at the time of referral were not included.

Data collection

Indicators of clinical care and treatment received, adverse events (including drug toxicities, immune reconstitution syndromes and treatment modifications), and virologic treatment outcomes were abstracted from electronic medical records through June 2015, allowing six months or more of follow-up after initial referral for all patients included in this study. Engagement in care was defined as having kept an appointment within the prior 6 months at

the time of dataset closure; loss-to-follow-up at this timepoint was defined as not being engaged in care and not having a documented transfer of care. Viral load and viral genotype data were only recorded as these were obtained clinically and available in the medical record. Genotyping involved sequencing of HIV reverse transcriptase and protease genes; HIV integrase sequencing was not routinely available at the time.

Statistical analysis

To assess whether the RAPID intervention impacted acceptability, safety, or short term efficacy of antiretroviral treatment, the primary analyses compared outcomes in the patients who were managed under the RAPID program protocol to those in patients referred to Ward 86 during the same time period but who were not managed under the RAPID program. Categorical characteristics were compared using Pearson's chi square or Fisher's Exact test where expected cell sizes were ≤5. Continuous variables were compared with a Student's t test. HIV-1 viral load (copies/mL) was log10 transformed for analyses. Data on time to first clinic visit, first primary care provider (PCP) visit, ART initiation, and viral suppression were complete through January 31, 2015 and were censored on that date (or, for patients known to have transferred care, on the date of the last available viral load test result). Data on ART safety and clinic appointment attendance were complete through June 1, 2015.

Time to viral suppression was defined as time from clinic referral to the first lab result with VL<200 copies/mL. Suppression was defined at this threshold [10] to allow for consistency across eras since the sensitivity of quantification assays changed over time. Median survival times with 95% confidence intervals were estimated using Kaplan-Meier estimators.

For the first main analysis, direct comparisons between RAPID program patients and the contemporaneous comparison group were made using the log rank test, and then followed up with Cox proportional hazards models, which allowed comparisons to be adjusted for integrase strand transfer inhibitor (INSTI)-based ART and baseline viral load. Because viral suppression could not be observed in patients who did not return to clinic at regular intervals, a competing risk regression model of time to viral suppression was conducted as an additional secondary analysis using the method of Fine and Gray [12]. For the competing risk regression, patients who were not observed to have VL<200 copies/mL by the time of their last available measurement and whose most recent viral load measurement was >6 months before the end of data collection in the initial phase of the study were considered to have the competing risk outcome.

The second (pre-and post-intervention) comparative analysis compared times to care milestones in the RAPID intervention cohort with similar data from a retrospective cohort of patients who were randomly sampled from the 2006–2009 "CD4-guided ART" era and the 2010–2013 "universal ART" era. This analysis paralleled the primary analysis and included graphing a Kaplan-Meier curve illustrating the proportions of patients achieving viral suppression over time from clinic referral in these three patient groups. Analyses were performed using Stata version 13.1. (Stata Corp., College Station, TX).

RESULTS

Patient characteristics

Among 86 outpatients referred for initiation of HIV care with newly diagnosed HIV infection, 39 were managed according to the RAPID intervention program and 47 received the clinic standard of care. None had private health insurance and only 8.1% reported previously having a primary care provider at the time they were referred. As shown in Table 1, most patients were male and of non-white race; patients frequently reported homelessness (27.9%), major mental health disorders (41.9%) and illicit substance use (41.9%). The demographic characteristics were similar between RAPID and non-RAPID groups. CD4+ T-cell count and viral load distributions were also similar for RAPID and non-RAPID patients. As expected, there was a substantially higher proportion of patients with acute or recent HIV infection in the RAPID group. In the RAPID group, 25.0% of patients with testing history documented were diagnosed with RNA positive/antibody-negative acute HIV infection and an additional 50.0% met had recent infection as defined by a prior negative HIV test within 6 months of their positive test date; in total 75.0% of the RAPID group therefore had acute or recent HIV infection. Document review also revealed 6.3% acute infections and 21.8% recent infections among the non-RAPID group (status that was not recognized at the time of referral).

Acceptance of RAPID ART

As shown in Figure 2,35 (89.7%) of 39 patients offered ART at their RAPID visit took the first dose in the clinic, and 37 (94.9%) had started ART within the first 24 hours following the visit. Differences in the achievement of key milestones of care among patient groups are shown in Table 2—times to each milestone are reported indexed either to the referral date (i.e., the date the clinic was contacted by the testing site) or to the date the diagnostic test sample was drawn. Referrals to RAPID occurred a median of 6 days (25–75th IQR: 2 to 11) after the HIV test, and typically occurred on the same day that HIV results were disclosed to the patient. Following referral, clinic intake and ART prescription both occurred a median of 1 day later for RAPID patients. Among non-RAPID patients, times to clinic intake and ART prescription were 10 and 22 days respectively ($p<0.001$).

Safety of RAPID ART

Most patients received INSTI-based ART, and the proportion receiving INSTI-based therapy was comparable between groups (RAPID patients, 89.7% vs. non-RAPID patients, 84.2%; $p=0.52$). The most common initial RAPID regimen was tenofovir disoproxil fumarate (TDF) plus emtricitabine plus dolutegravir, used in 66.7% of patients. ART regimen modifications were significantly more frequent among RAPID patients: in two RAPID cases ART was changed due to a rash, whereas in ten cases ART was changed for simplification (e.g. to an abacavir-lamivudine-dolutegravir single pill regimen) following receipt of the results of HLA B5701 testing. There were no ART modifications for virologic failure and no resistance-driven ART changes after genotype results became available.

Among 75 patients for whom resistance genotype information was available, transmitted drug resistance mutations were present in 26 (34.7%), with a major NNRTI mutations

present in 18 (24.0%) individuals (Table 2). Ability to obtain genotypes at follow-up visits was limited by rapid viral suppression. Integrase genotyping for INSTI resistance mutations was not available to clinicians during the evaluation period. We observed no cases in which major mutations were present to the prescribed ART regimen.

Engagement and retention in care

Transfer of care to another HIV clinic occurred in 8 (20.5%) of 39 patients in the RAPID group, and similarly, in 11 (23.4%) of 47 patients in the non-RAPID group. Loss to follow-up was also similar, occurring in 4 (10.3%) of 39 RAPID and 7 (14.9%) of 47 non-RAPID patients (p=0.52). No patients continuing in care at the clinic requested a change in their assigned provider.

Viral suppression

Data on time to viral suppression for RAPID and non-RAPID patient groups are shown in Table 2. Viral load measurements occurred with a median interest interval of 58 days (IQR: 47 to 83) and there were no differences between RAPID and concurrent non-RAPID groups (p=0.57). The median time to viral suppression (<200 copies/mL) in RAPID patients was 56 days from clinic referral, compared with 79 days among the non-intervention participants (p=0.009). Differences remained statistically significant when controlling for baseline viral load and integrase inhibitor use. When loss-to-follow-up was considered as a competing risk in sensitivity analyses, faster suppression in the RAPID group remained statistically significant. The second, pre- and post- intervention analysis compared RAPID ART initiation with ART initiation by primary providers under CD4-guided and universal ART recommendations in previous years. Figure 3 illustrates this Kaplan-Meier analysis. The median of 1.8 months from referral to viral suppression under RAPID contrasted with 4.3 months in the pre-RAPID, universal ART group, and 7.2 months in the CD4-guided ART group (p=0.0001).

DISCUSSION

In this study, we found that a health systems intervention to initiate antiretroviral therapy (ART) on the same day as HIV diagnosis was highly feasible in a real-world public health clinic in San Francisco. Same-day, observed initiation of antiretroviral treatment was well accepted, was well tolerated by patients, and did not appear to interfere with subsequent engagement in care. Among patients treated under recommendations for universal initiation of ART, receiving the intervention was further associated with a shorter duration of time to viral suppression: the time from referral to viral suppression was reduced from 4.3 months in non-intervention recipients to 1.8 months in those receiving the same-day ART intervention.

This intervention utilized a streamlined HIV treatment initiation model that is similar in important respects to models used in the treatment of other communicable diseases. We found that the use of same-day, observed dosing on the day of diagnosis, medication starter packs, and use of pre-approved regimens were all feasible for patients with newly-diagnosed HIV.

However, we also found that starting ART immediately required additional time from all members of our multidisciplinary team. Our new patients lacked health insurance and often had immediate housing, substance use or mental health treatment needs. The addition of same-day ART into the first clinic visit therefore increased the urgency of arranging health insurance and also compressed the time available for social workers to begin the process of psychological and social stabilization. Because ART was begun without some baseline laboratory results available, there were also intensified demands on clinical providers to consider early regimen modifications. While a RAPID approach is clearly feasible, additional work will be needed to demonstrate optimal systems for implementation in different practice settings.

There are several additional limitations to this non-randomized implementation study. First, because all subjects received a multi-component intervention, we were unable to determine which specific components (such as same-day appointments, or observed dosing) contributed to positive patient outcomes. It is therefore unclear whether programs that omit one or more of these elements could expect similar outcomes. Second, it is possible that faster virologic suppression rates among RAPID intervention recipients could be explained by unmeasured differences between the patients who were selected for the intervention and those who were not selected. However, the only differences evident between groups were higher baseline HIV viral load and more frequent acute and recent HIV infection in the intervention group—differences that are not expected to lead to faster rates of suppression.

However the fact that the intervention was feasible in the setting of acute and recent HIV infection is especially encouraging. An intensive RAPID approach may be particularly valuable in the setting of acute infection—during which immediate treatment can reduce HIV reservoir size [13,14] reduce complications [15] and eliminate acute phase transmission [16–20] which may drive urban epidemics [20].

In summary, these results provide evidence that prioritizing immediate ART initiation can reduce the time to achieving virologic suppression in newly diagnosed patients without negative consequences to the patient. A shorter time to viral suppression offers both clinical benefits to patients, but also prevention benefits to the community. More detailed studies are needed to examine the optimal design, overall impact and cost-effectiveness of scaled up strategies for RAPID ART initiation.

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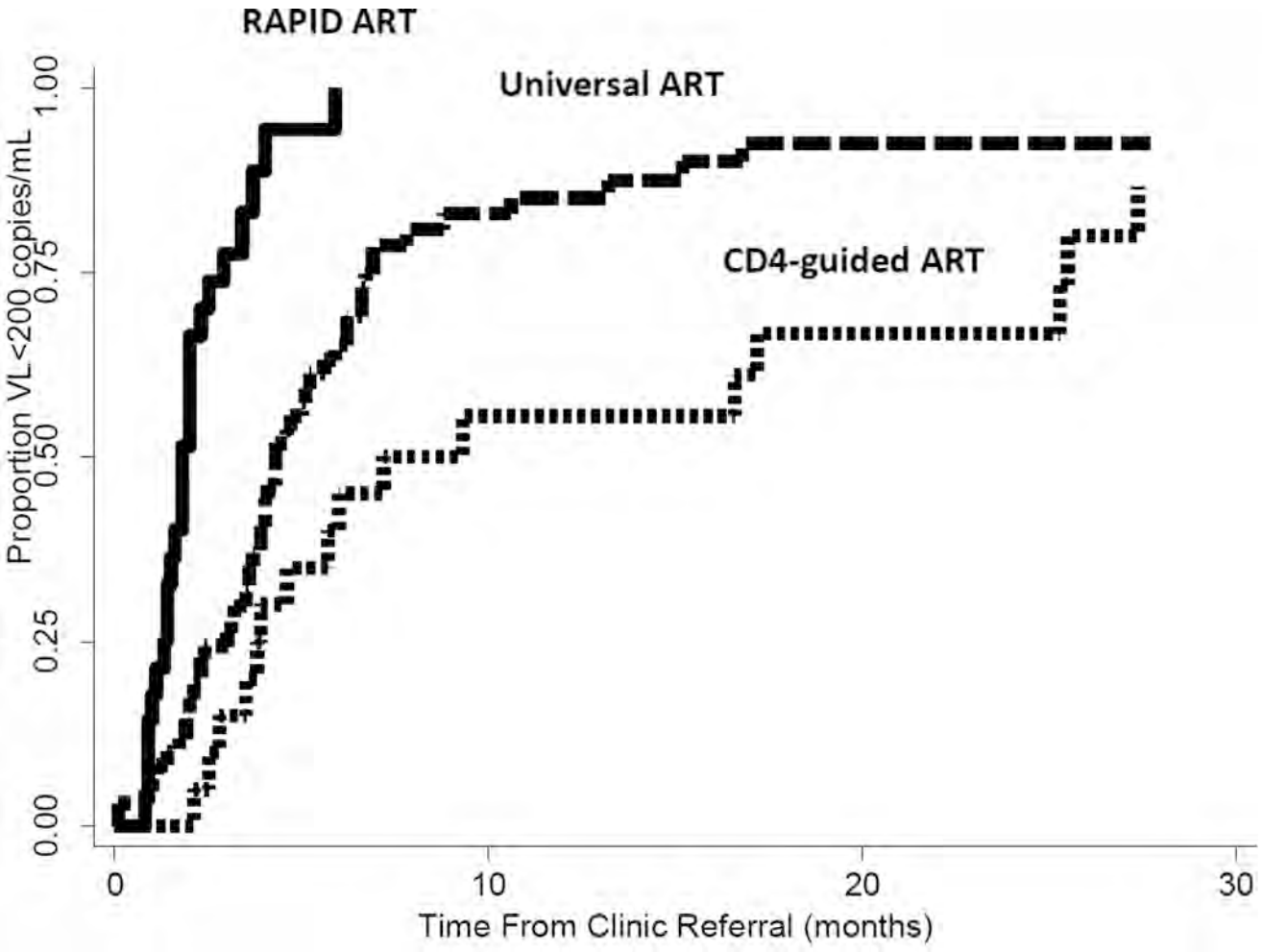

Figure 1. Standard of care and RAPID program models for initiation of outpatient antiretroviral therapy

In the RAPID model, a time-intensive "RAPID" visit was performed as soon as possible following a new diagnosis of HIV. ART was initiated by a RAPID program provider so that the first encounter with the assigned primary provider involved ART management. In the standard model ART was initiated by the primary provider after preparatory visits involving clinic intake, social, psychological, medical and laboratory evaluation.

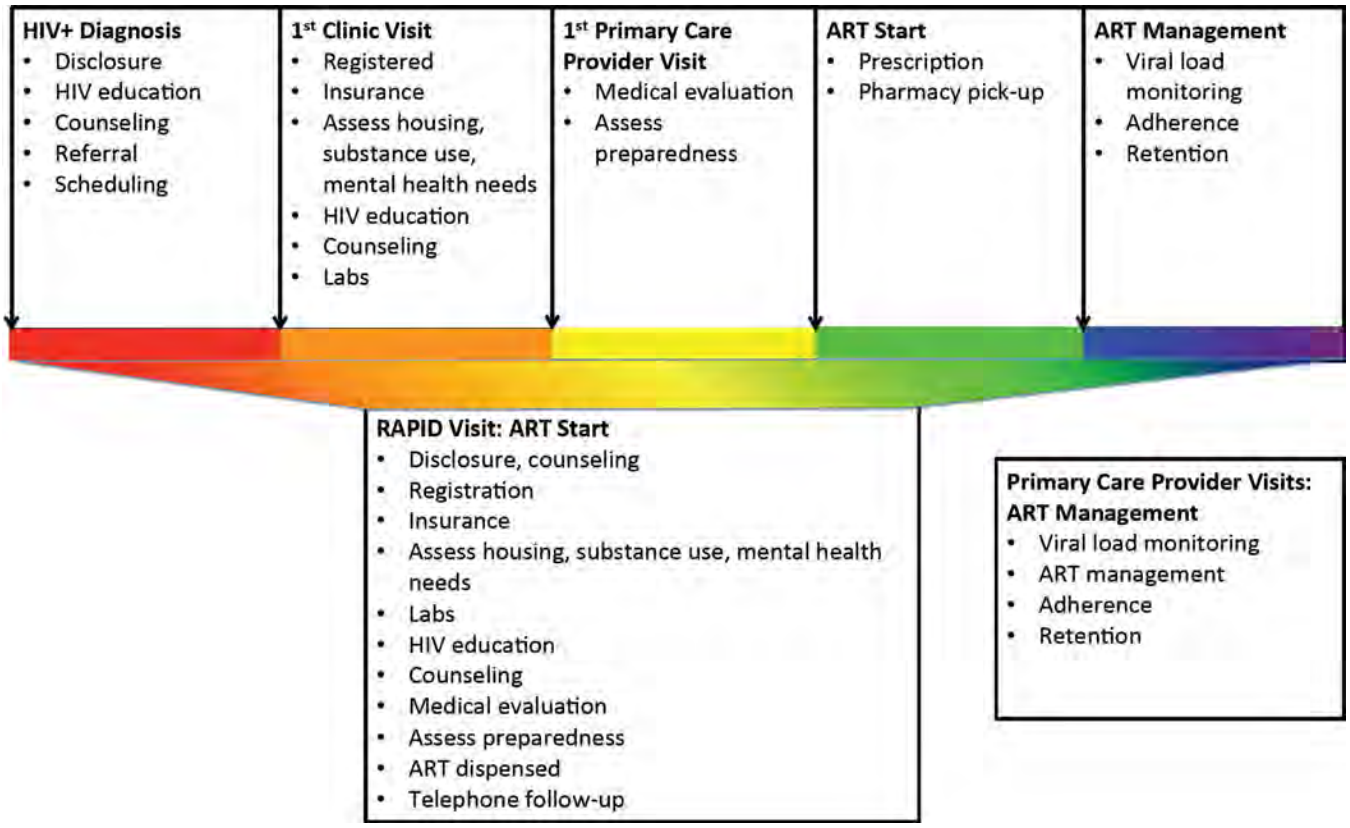

Figure 2. Uptake of ART when offered immediately after diagnosis

Data shown are for patients with a new HIV diagnosis and attending their first visit to the SFGH HIV Ciinic between 2013 and 2015 during the RAPID intervention program period. The percentage of patients choosing to take ART when offered by RAPID is shown by the black bars: ninety-five percent (37/39) patients elected to begin ART within a day of its being offered. Slower uptake among non-RAPID patients is related to the deferral of the offer to start ART.

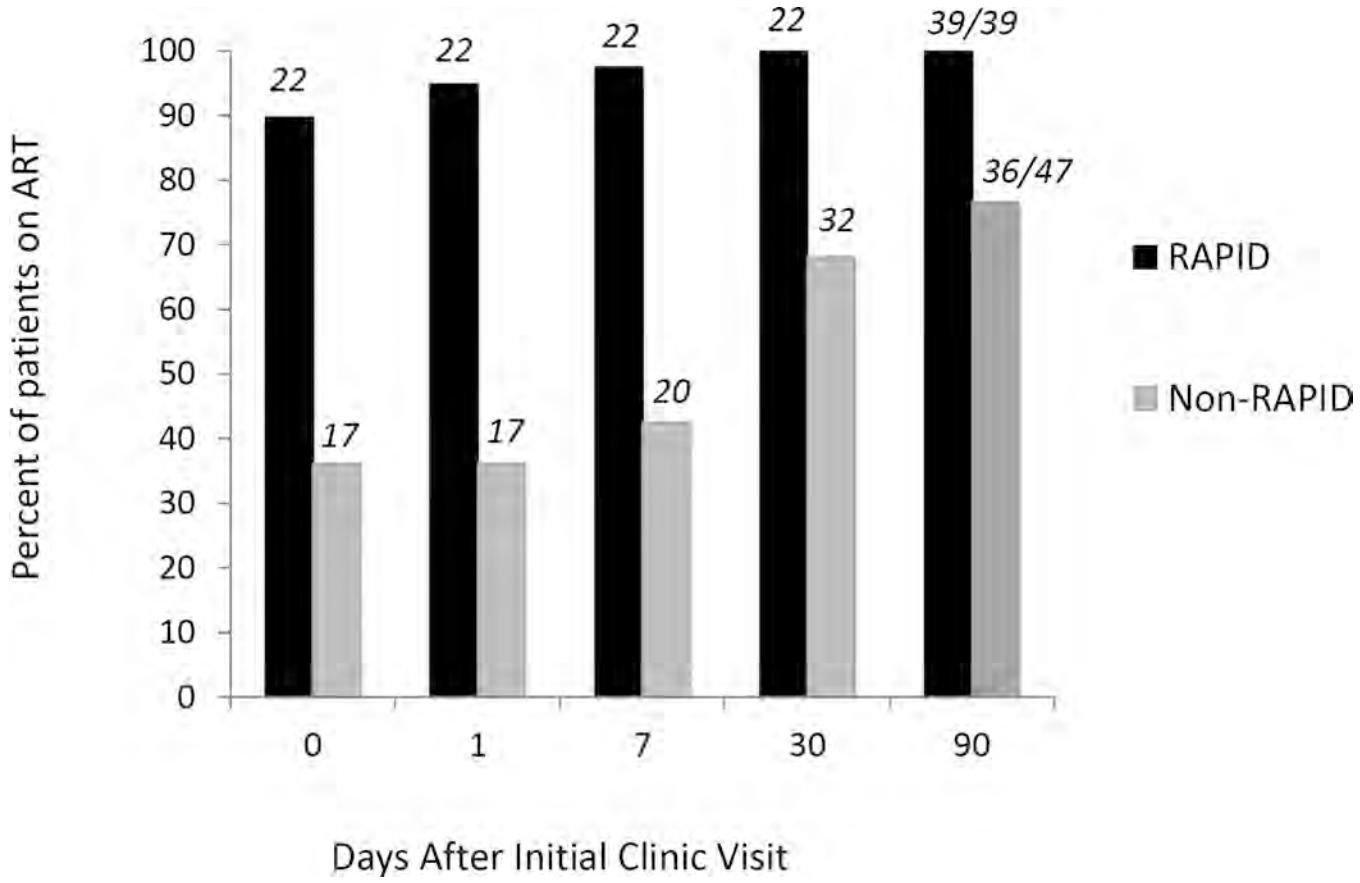

Figure 3. Time to viral suppression among patients newly diagnosed with HIV infection, by ART initiation strategy

This Kaplan-Meier plot shows the proportion of patients with viral load <200 copies/mL HIV RNA over time, following referral to the SFGH HIV clinic with a new diagnosis of HIV infection. Time to suppression for patients receiving the RAPID intervention in 2013–2015 (median 1.8 months) was significantly shorter than for patients treated under universal ART guidelines in the immediate pre-RAPID 2010–2013 period (4.3 months, p<.0001) and in the previous CD4 guided 2006–2009 period (7.2 months, p<.0001) represented by dotted line.

Table 1

Patient characteristics and ART use among 86 newly diagnosed patients referred to the San Francisco General Hospital HIV Clinic

Results are compared between 39 patients treated in the RAPID program for same-day, observed initiation of ART and 47 patients treated according to the clinic standard of care.

Characteristic	RAPID N=39	Non-RAPID N=47	p-value
Sociodemographic			
Age, mean (range)	31.6 (21 to 47)	34.8 (19 to 68)	0.14
Race/ethnicity, n (%)			0.034
Black	2 (5.1%)	12 (25.5%)	
Latino	18 (46.2%)	15 (31.9%)	
White	16 (41.0%)	13 (27.7%)	
Asian/Pacific Islander	3 (7.7%)	7 (14.9%)	
Sex, n (%)			0.11
Male	39 (100.0%)	44 (93.6%)	
Female	0 (0.0%)	3 (6.4%)	
Mental Health, n (%)			
Major disorder present	21 (53.9%)	15 (31.9%)	0.04
Housing, n (%)			0.97
Stably Housed	25 (64.1%)	31 (66.0%)	
Homeless	11 (28.2%)	13 (27.7%)	
Unknown	3 (7.7%)	3 (6.4%)	
Illicit Substance Use, n (%)			
Any reported	18 (46.2%)	18 (38.3%)	0.75
Clinical characteristics			
Baseline CD4 cell count[1], mean (range)	474 *(3 to 1391)*	417 *(11 to 1194)*	0.38
Baseline HIV RNA viral load[2], mean (range)	4.89 (*2.76 to 6.61)*	4.49 (*1.60 to 6.08)*	0.082
Acute or recent HIV Infection[3], n/N (%)			
Acute (RNA positive/Ab negative)	8/32 (*25.0%)*	2/32 (*6.3%)*	0.041
Recent (Ab negative within 6 months)	24/32 (*75.0%)*	9/32 (*28.1%)*	<0.001
Transmitted resistance			
Genotype obtained	32/39 (82.1%)	43/47 (91.5%)	0.21
Any[4]	8/32 (25.0%)	18/43 (41.9%)	0.13
Major NNRTI-R[4]	7/32 (21.9%)	11/43 (25.6%)	0.71
Major PI-R	1/32 (3.1%)	2/43 (4.7%)	0.99
Major NRTI-R	0 (0%)	1/43 (2.3%)	0.99
ART initiated[5,6]	39/39 (100%)	38/47 (80.9%)	0.003
INSTI use[6]	35/39[4] (89.7%)	32/38 (84.2%)	0.47
PI Use[6]	5/39 (12.8%)	5/38 (13.2%)	0.97
NNRTI use[6]	0/39 (0%)	3/38 (7.9%)	0.12

[1]Baseline CD4 T cell count units: cells/mm3

[2]Baseline HIV RNA Viral Load units: log10(copies/mL)

[3]Acute HIV infection status was defined by having a negative or indeterminate antibody test for HIV on the date of an initial positive test. Recent HIV infection status was defined by <6 months between diagnosis and prior negative HIV test result, which was known for only n=64/86 patients (74.4%) and among that overall group the proportion with acute or recent infection was 33/64 patients (51.8%). If known at the time of referral this was one indication for RAPID program enrollment.

[4]Presence of any RT or protease mutations consistent with transmitted drug resistance determined using current Stanford surveillance definitions. Major mutations conferring clinically significant resistance to given medications used current Stanfod clinical resistance definitions; there were 14 K103N, 3 V179D, and 1 V106A NNRTI mutations observed; only 2 major PI mutations (1 I54V, 1 L90M); and one virus with M184V. No K65R or T215F/Y mutations were observed and no 2 class resistant viruses were seen. Integrase resistance testing was not clinically available and was not performed.

[5]ART initiation documented at any time up to the time of maximum follow-up in June 2015 (at least six months after referral of the last patient included in the analysis).

[6]INSTI=integrase strand transfer inhibitor; PI=protease inhibitor; NNRTI=non-nucleoside reverse transcriptase inhibitor. The most common regimen initiated in RAPID patients was truvada (tenofovir disoproxil fumarate/emtricitabine) plus dolutegravir (in 26 patients); others included stribild (tenofovir/emtricitabine/elvitegravir/cobicistat) in 7 patients; truvada plus darunavir plus ritonavir (4 patients); truvada plus raltegravir (1 patient) and triumeq (abacavir plus lamivudine plus dolutegravir) in 1 patient.

Table 2

Time to achievement of clinical milestones among newly diagnosed patients referred to the San Francisco General Hospital HIV Clinic

Outcomes are compared between patients who were offered the RAPID intervention and those who were not offered the intervention but who received an otherwise similar standard of care, either during the same time frame (the "non-RAPID" comparison group) or under evolving treatment guidelines during the years prior to the RAPID program.

Group	**RAPID**	**Non-RAPID**	**Universal ART era**	**CD4-guided era**	**Between-group comparisons**	
Referral years	2013–2014	2013–2014	2010–2013	2006–2009	RAPID vs. non-RAPID	RAPID vs. 2010–2013 Universal
Patients for whom ART recommended	All	All	All	CD4<500	(contemporaneous)	(pre-post intervention)
Received intervention	Yes	No	No	No		
N:	39	47	69	25	p-values[1]	
Time in days from referral to:						
Clinic intake visit	1 (0–5)	10 (7–17)	13 (7–26)	9 (2 – 44)	<0.001	<0.001
Primary provider visit	14 (3 –30)	26 (13 –105)	31 (17–60)	30 (7–65)	0.13	0.089
ART prescription	1 (0–7)	22 (14–48)	37 (26–148)	128 (39–520)	<0.001	<0.001
Viral suppression <200 cp/mL	56 (40–87)	79 (53–174)	132 (91–210)	218 (116–777)	0.009	<0.001
Time in days from diagnosis to:						
Referral to the clinic	6 (2–11)	11 (3–104)	14 (4–48)	33 (4–120)	0.004	0.008
Viral suppression <200 cp/mL	65 (52–119)	170 (79 – 363)	190 (113–302)	580 (138–971)	<0.001	<0.001

[1] P-values shown did not consider loss to follow-up as a competing risk (see text).