FY 2020 Houston EMA Ryan White Part A/MAI Service Definition **Clinical Case Management**	
HRSA Service Category Title: **RWGA Only**	**Medical Case Management**
Local Service Category Title:	**Clinical Case Management (CCM)**
Budget Type: **RWGA Only**	**Unit Cost**
Budget Requirements or Restrictions: **RWGA Only**	Not applicable.
HRSA Service Category Definition: **RWGA Only**	***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.
Local Service Category Definition:	**Clinical Case Management**: Identifying and screening clients who are accessing HIV-related services from a clinical delivery system that provides Mental Health treatment/counseling and/or Substance Abuse treatment services; assessing each client's medical and psychosocial history and current service needs; developing and regularly updating a clinical service plan based upon the client's needs and choices; implementing the plan in a timely manner; providing information, referrals and assistance with linkage to medical and psychosocial services as needed; monitoring the efficacy and quality of services through periodic reevaluation; 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 HCPHS/RWGA policies.
Target Population (age,	Services will be available to eligible HIV-infected clients residing in

gender, geographic, race, ethnicity, etc.):	the Houston EMA with priority given to clients most in need. All clients who receive services will be served without regard to age, gender, race, color, religion, national origin, sexual orientation, or handicap. Services will target low income individuals with HIV/AIDS who demonstrate multiple medical, mental health, substance use/abuse and psychosocial needs including, but not limited to: mental health counseling (i.e. professional counseling), substance abuse treatment, primary medical care, specialized care, alternative treatment, medications, placement in a medical facility, emotional support, basic needs for food, clothing, and shelter, transportation, legal services and vocational services. Services will also target clients who cannot function in the community due to barriers which include, but are not limited to, mental illness and psychiatric disorders, drug addiction and substance abuse, extreme lack of knowledge regarding available services, inability to maintain financial independence, inability to complete necessary forms, inability to arrange and complete entitlement and medical appointments, homelessness, deteriorating medical condition, illiteracy, language/cultural barriers and/or the absence of speech, sight, hearing, or mobility. *Clinical Case Management* is intended to serve eligible clients, especially those underserved or unserved population groups which include: African American, Hispanic/Latino, Women and Children, Veteran, Deaf/Hard of Hearing, Substance Abusers, Homeless and Gay/Lesbian/Transsexual.
Services to be Provided:	Provision of Clinical Case Management activities performed by the Clinical Case Manager. *Clinical Case Management* is a working agreement between a client and a Clinical Case Manager for a defined period of time based on the client's assessed needs. *Clinical Case Management* services include performing a comprehensive assessment and developing a clinical service plan for each client; monitoring plan to ensure its implementation; and educating client regarding wellness, medication and health care compliance in order to maximize benefit of mental health and/or substance abuse treatment services. The *Clinical Case Manager* serves as an advocate for the client and as a liaison with mental health, substance abuse and medical treatment providers on behalf of the client. The Clinical Case Manager ensures linkage to mental health, substance abuse, primary medical care and other client services as indicated by the clinical service plan. The Clinical Case Manager will perform *Mental Health* and *Substance Abuse/Use Assessments* in accordance with RWGA Quality Management guidelines. Service plan must reflect an ongoing discussion of mental health treatment and/or substance abuse treatment, primary medical care and medication adherence, per client need. *Clinical Case Management is* both office and community-based. Clinical

	Case Managers will interface with the primary medical care delivery system as necessary to ensure services are integrated with, and complimentary to, a client's medical treatment plan.
Service Unit Definition(s): **RWGA Only**	One unit of service is defined as 15 minutes of direct client services and allowable charges.
Financial Eligibility:	Refer to the RWPC's approved *Financial Eligibility for Houston EMA Services*.
Client Eligibility:	HIV-infected individuals residing in the Houston EMA.
Agency Requirements:	*Clinical Case Management* services will comply with the HCPHS/RWGA published Clinical Case Management Standards of Care and policies and procedures as published and/or revised, including linkage to the CPCDMS data system *Clinical Case Management Services* must be provided by an agency with a documented history of, and current capacity for, providing mental health counseling services (categories b., c. and d. as listed under *Amount Available* above) or substance abuse treatment services to PLWH/A (category a. under *Amount Available* above) in the Houston EMA. Specifically, an applicant for this service category must clearly demonstrate it has provided mental health treatment services (e.g. professional counseling) or substance abuse treatment services (as applicable to the specific CCM category being applied for) in the previous calendar or grant year to individuals with an HIV diagnosis. Acceptable documentation for such treatment activities includes standardized reporting documentation from the County's *CPCDMS* or Texas Department of State Health Services' *ARIES* data systems, Ryan White Services Report (RSR), SAMSHA or TDSHS/SAS program reports or other verifiable <u>published</u> data. Data submitted to meet this requirement is subject to audit by HCPHS/RWGA prior to an award being recommended. **Agency-generated non-verifiable data is not acceptable.** In addition, applicant agency must demonstrate it has the capability to continue providing mental health treatment and/or substance abuse treatment services for the duration of the contract term and any subsequent one-year contract renewals. Acceptable documentation of such continuing capability includes <u>current</u> funding from Ryan White (all Parts), TDSHS HIV-related funding (Ryan White, State Services, State-funded Substance Abuse Services), SAMSHA and other ongoing federal, state and/or public or private foundation HIV-related funding for mental health treatment and/or substance abuse treatment services. Proof of such funding must be documented in the application and is subject to independent verification by HCPHS/RWGA prior to an award being recommended. Loss of funding and corresponding loss of capacity to provide mental health counseling or substance abuse treatment services as applicable may result in the termination of Clinical Case Management Services

	awarded under this service category. Continuing eligibility for Clinical Case Management Services funding is explicitly contingent on applicant agency maintaining verifiable capacity to provide mental health counseling or substance abuse treatment services as applicable to PLWH/A during the contract term. **Applicant agency must be Medicaid and Medicare Certified**.
Staff Requirements:	Clinical Case Managers must spend at least 42% (867 hours per FTE) of their time providing direct case management services. Direct case management services include any activities with a client (face-to-face or by telephone), communication with other service providers or significant others to access client services, monitoring client care, and accompanying clients to services. Indirect activities include travel to and from a client's residence or agency, staff meetings, supervision, community education, documentation, and computer input. Direct case management activities must be documented in the Centralized Patient Care Data Management System (CPCDMS) according to CPCDMS business rules. *Must comply with applicable HCPHS/RWGA Houston EMA/HSDA Part A/B Ryan White Standards of Care:* Minimum Qualifications: **Clinical Case Managers** must have at a minimum a Bachelor's degree from an accredited college or university with a major in social or behavioral sciences and have a current and in good standing State of Texas license (LBSW, LSW, LMSW, LCSW, LPC, LPC-I, LMFT, LMFT-A or higher level of licensure). The Clinical Case Manager may supervise the Service Linkage Worker. CCM targeting Hispanic PLWHA must demonstrate both written and verbal fluency in Spanish. Supervision: The **Clinical Case Manager** (CCM) must function with the clinical infrastructure of the applicant agency and receive supervision in accordance with the CCM's licensure requirements. At a minimum, the CCM must receive ongoing supervision that meets or exceeds HCPHS/RWGA published Ryan White Part A/B Standards of Care for Clinical Case Management. If applicant agency also has Service Linkage Workers funded under Ryan White Part A the CCM may supervise the Service Linkage Worker(s). Supervision provided by a CCM that is not client specific is considered **indirect time** and is not billable.
Special Requirements: **RWGA Only**	Contractor must employ full-time Clinical Case Managers. Prior approval must be obtained from RWGA to split full-time equivalent (FTE) CCM positions among other contracts or to employ part-time staff. **Contractor must provide to RWGA the names of each Clinical Case Manager and the program supervisor no later than 3/30/17. Contractor must inform RWGA in writing of any**

	changes in personnel assigned to contract within seven (7) business days of change. Contractor must comply with CPCDMS data system business rules and procedures. Contractor must perform CPCDMS new client registrations and registration updates for clients needing ongoing case management services as well as those clients who may only need to establish system of care eligibility. Contractor must issue bus pass vouchers in accordance with HCPHS/RWGA policies and procedures.

FY 2021 RWPC "How to Best Meet the Need" Decision Process

Step in Process: **Council**		Date: **06/11/2020**
Recommendations:	Approved: Y:_____ No: ______ Approved With Changes:______	If approved with changes list changes below:
1.		
2.		
3.		
Step in Process: **Steering Committee**		Date: **06/04/2020**
Recommendations:	Approved: Y:_____ No: ______ Approved With Changes:______	If approved with changes list changes below:
1.		
2.		
3.		
Step in Process: **Quality Improvement Committee**		Date: **05/19/2020**
Recommendations:	Approved: Y:_____ No: ______ Approved With Changes:______	If approved with changes list changes below:
1.		
2.		
3.		
Step in Process: **HTBMTN Workgroup #1**		Date: **04/21/2020**
Recommendations:	Financial Eligibility:	
1.		
2.		
3.		

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Building a Healthy Community

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FY 2018 PERFORMANCE MEASURES HIGHLIGHTS
RYAN WHITE GRANT ADMINISTRATION
HARRIS COUNTY PUBLIC HEALTH (HCPH)

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Summary Reports for all Services

Highlights from FY 2018 Performance Measures

Measures in this report are based on the 2018/2019 Houston Ryan White Quality Management Plan, Appendix B. HIV Performance Measures.

Clinical Case Management

- During FY 2018, from 3/1/2018 through 2/28/2019, 1,096 clients utilized Part A clinical case management. According to CPCDMS, 542 (50%) of these clients accessed primary care two or more times at least three months apart during this time period after utilizing clinical case management.
- Among these clients, 30% accessed mental health services at least once during this time period after utilizing clinical case management.
- For clients who have lab data in CPCDMS, 79% were virally suppressed.

Ryan White Part A
HIV Performance Measures
FY 2018 Report

Clinical Case Management
All Providers

For FY 2018 (3/1/2018 to 2/28/2019), 1,096 clients utilized Part A clinical case management.

HIV Performance Measures	**FY 2017**	**FY 2018**	**Change**
A minimum of 75% of clients will utilize Part A/B/C/D primary care two or more times at least three months apart after accessing clinical case management	632 (50.0%)	542 (49.5%)	**-0.5%**
35% of clinical case management clients will utilize mental health services	328 (25.9%)	328 (30.0%)	**4.1%**
75% of clients for whom there is lab data in the CPCDMS will be virally suppressed (<200)	466 (71.1%)	453 (78.6%)	**7.5%**
Less than 15% of clients will be homeless or unstably housed	217 (17.2%)	164 (15.0%)	**-2.2%**

According to CPCDMS, 15 (1.4%) clients utilized primary care for the first time and 80 (7.3%) clients utilized mental health services for the first time after accessing clinical case management.

Clinical Chart Review Measures	**FY 2017**
85% of clinical case management clients will have a case management care plan developed and/or updated two or more times in the measurement year	*NA
Percentage of clients identified with an active substance abuse condition receiving Ryan White funded substance abuse treatment	*NA

*Clinical Case Management chart review was not performed for FY 2017 – review will be performed starting with FY 2018.

Harris County
Public Health
Building a Healthy Community

Ryan White Part A
Quality Management Program- Houston EMA
Case Management Chart Review FY 18
Ryan White Grant Administration

CUMMULATIVE SUMMARY, DE-IDENTIFIED

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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 609 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, 2018- February 28, 2019. The chart review was conducted by the Project Coordinator for Quality Management Development, a Licensed Master Social Worker on the Ryan White Grant Administration team. 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.

While traditional, community-based case management models tend to provide intensive, individualized assistance to a limited and defined number of clients on a social worker's "case load," case management in this time and place resembles more of a "revolving door" model. This evolution is not unique to the Ryan White system of care. The National Association of Social Workers has identified this transformation of case management in the health care setting as a growing challenge for medical social workers[1]. Social workers have become sought out by health care institutions in order to add professionals to their practice who specialize in holistic, person-centered approaches. However, as the health care system itself changes, the role of a medical case managers has adapted to include the more administrative tasks that are necessary for managed care facilitates and reimbursement models to function.

In practical terms, this means that case managers are now more often performing tasks that registered nurses, benefits specialists, and medical assistants are equally skilled to perform, such as scheduling and reminders, basic health education, and insurance or coverage navigation. While it is clear that these are invaluable functions in the HIV treatment setting, it is a distinct shift away from the type of psychosocial work that social workers are trained to do, such as supportive counseling, task-centered motivational change, service planning and intensive follow-up, and accompaniment through the social services system. Unfortunately, as the HIV epidemic shifts to disproportionately impact low-income, marginalized communities with lower social capital and higher incidence of mental health concerns, this the exact type of professional help that is sorely underutilized in HIV care.

[1] National Association of Social Workers. (2016). *NASW Standards for Social Work Practice in Health Care Settings*.

While this description is certainly not true of all agencies or client records reviewed, the data presented in this year's chart review paints an overall picture of a case management system that is characterized by in-the-moment, on-demand requests, rather than ongoing contact at regular intervals. More than half of the clients in the sample (56%) had 3 or less interactions from a case manager within the review year and less than 11% of the medical case management clients received two "care plans" within the year. These findings are consistent with last year's review, in which the previous chart abstractor noted that, "the Ryan White Standards of Care seem to presume much more intense and frequent contact between case manager and client than is actually happening in practice."

At the individual agency level, there are many noteworthy and innovative practices that were highlighted throughout the chart review process and quality management site interviews. For example, a lead case manager at one agency regular conducts chart review on the next day's patients in order to brief and essentially "pre-round" with the medical provider on their patient list. Another agency engages clients in their own assessments by having the patient self-administer the form so that it may be used as a conversation starter and way to build rapport, rather than a "cold interview" technique. Yet another agency has adapted their physical clinic layout to utilize a "pod" model in which at least one medical case manger and one service linkage worker is assigned to a provider, which functionally and closely resembles a case load model. One agency has an entirely separate benefits department that handles eligibility and enrollment for coverage programs, freeing up that responsibility from the case management team. All of these practices highlight opportunities and strengths within our Ryan White system for case management to continue as a value-added service for People Living with HIV.

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.

This tool has been developed with input from case management providers and previous chart abstractors and continues to be refined to prompt a more detailed chart review process. Since the tool and sample collection method continue to be revised each year, a retrospective comparison is not offered in this report, though previous reports are available upon request.

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 chart abstraction tool was also reviewed by the Ryan White Grant Administration Quality Management team, the supervisors of the case management staff at each agency, and a Clinical Quality Improvement committee convened by Ryan White Grant Administration.

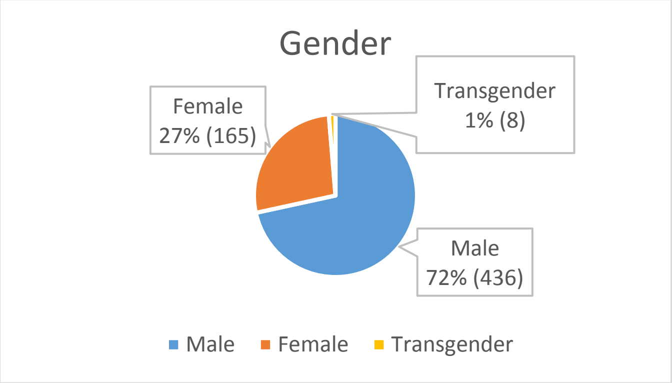
The Sample

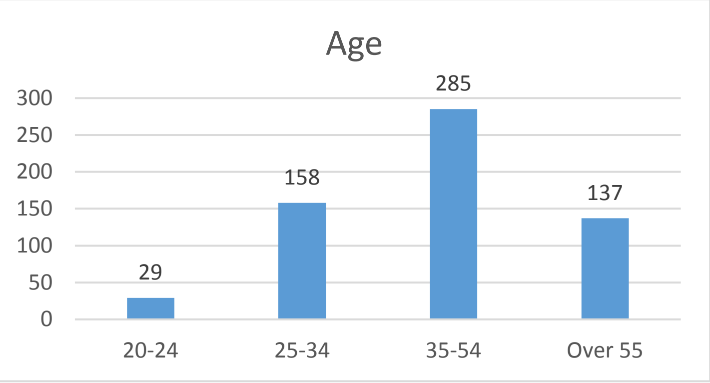
In order to conduct a thorough and comprehensive review, a total of 609 client records were reviewed across seven agencies for the 2018-2019 grant year. This included sixty (60) Clinical Case Management charts at a non-primary care site. In this Case Management Chart Review Report, any section that evaluated 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.

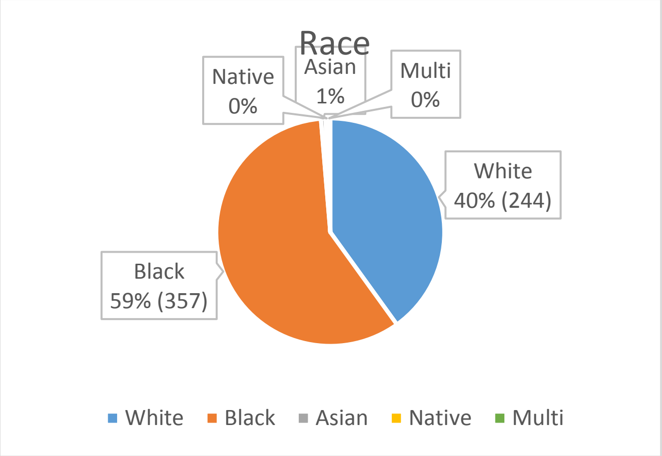
Agency	A	B	C	D	E	F	G
# of Charts Reviewed	67	105	97	70	105	105	60

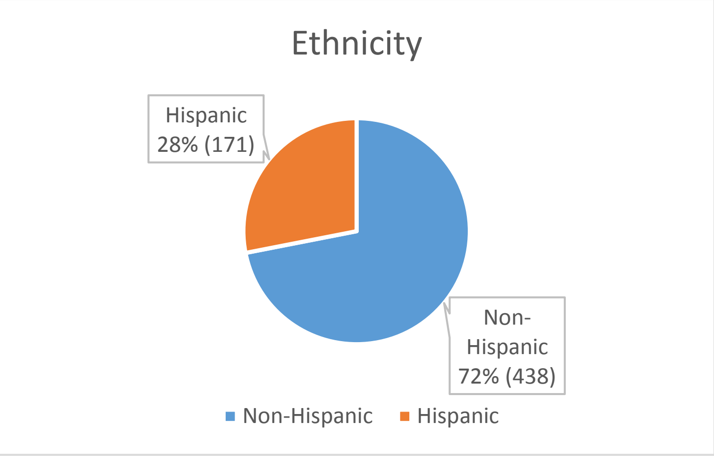
TOTAL 609 (549 excluding non-PCare site)

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, 2018- February 28, 2019 grant year was queried from the Centralized Patient Care Data Management System data base. The total eligible population from which the sample was drawn was a pool of 11,159 case management clients. The number of clients selected at each site is proportional to the number of case management clients served there. Each sample was determined to be comparable to the racial, ethnic, age, and gender demographics of each site's overall case management patient population.









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[2] New York Department of Health AIDS Institute. (2006). *HIVQUAL Workbook: Guide for quality improvement in HIV care*. NY: U.S. Department of Health and Human Services Health Resources and Services Administration HIV/AIDS Bureau.

Health insurance coverage type was also analyzed according to the client’s registration. More than half of the sample (55%) was uninsured; 24% was enrolled in either Medicaid, Medicare, or some combination; 7% had a private or commercial plan; and an additional 14% had an unknown insurance coverage status.

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, which is shared on page 9.

# of appointments	A	B	C	D	E	F	TOTAL
0 appts.	6 (9%)	14 (13%)	15 (15%)	1 (1%)	11 (10%)	7 (7%)	54 (10%)
1 appts.	12 (18%)	13 (12%)	20 (21%)	12 (17%)	26 (25%)	24 (23%)	107 (19%)
2 appt.	23 (34%)	17 (16%)	21 (22%)	37 (53%)	44 (42%)	34 (32%)	176 (32%)
3 + appts.	26 (39%)	61 (58%)	41 (42%)	20 (29%)	24 (23%)	40 (38%)	212 (39%)
TOTALS	*67* *(100%)*	*105* *(100%)*	*97* *(100%)*	*70* *(100%)*	*105* *(100%)*	*105* *(100%)*	*549* *(100%)*

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 (39%), followed by 32% of the clients having 2 appointments in the year, 19% having 1 appointment, and 10% of the sample having had 0 appointments.

CASE MANAGEMENT ENCOUNTERS

Frequency of case management encounters were also reviewed. The dates 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) and a general description of what was discussed during the encounter 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 (29%) within the year or more than 5 encounters (30%).

> *"Overall, the average number of case management encounters for the entire sample was **five (5)**."*

# of CM encounters	A	B	C	D	E	F	G	TOTAL
1	1 (2%)	23 (21%)	20 (21%)	29 (41%)	53 (50%)	33 (31%)	15 (25%)	174 (29%)
2	2 (3%)	22 (21%)	10 (10%)	17 (24%)	22 (21%)	21 (20%)	3 (5%)	97 (16%)
3	3 (4%)	15 (14%)	13 (13%)	8 (11%)	8 (8%)	16 (15%)	4 (7%)	67 (11%)
4	3 (4%)	14 (13%)	13 (13%)	5 (7%)	5 (5%)	7 (7%)	1 (2%)	48 (8%)
5	3 (4%)	9 (9%)	9 (9%)	7 (10%)	7 (7%)	3 (3%)	4 (7%)	42 (7%)
Over 5	55 (82%)	22 (21%)	32 (33%)	4 (6%)	10 (10%)	25 (24%)	33 (55%)	181 (30%)
TOTALS	*67* *(100%)*	*105* *(100%)*	*97* *(100%)*	*70* *(100%)*	*105* *(100%)*	*105* *(100%)*	*60* *(100%)*	*609* *(100%)*
Range	1-51	1-15	1-17	1-6	1-24	1-25	1-82	1-82
Average	11.8	3.75	5	2.4	2.8	4	11	5

29% of the clients in the sample had just one case management encounter within the review year while another 30% had more than five, with the highest amount of encounters for one client being 82 within the grant year. Overall, the average number of encounters for the entire sample was five case management encounters. Neither race nor gender had a significant impact on the average number of encounters. The average number of encounters for clients who had contact with a Medical Case Manager was double that of those who did not have contact with a Medical Case Manager throughout the year, at six and three encounters, respectively. The agency with the highest average frequency of case management encounters averaged nearly one encounter per month, at 11.8.

> *The average number of encounters for clients who had contact with a Medical Case Manager was **six**, while the average for those who did not work with an MCM was **three**.*

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."

Therefore, it is important to note that the "VL Suppression Rate" is presented in two different ways in the chart below. The top rate, in blue, is the more conservative analysis of the percentage of clients who were coded as "Suppressed." In other words, it is the percentage of clients within the sample who were suppressed for *all* of their recorded labs during the year, which could be loosely interpreted as "durably suppressed." The second VL Suppression Rate offered in red is the more standardly used HRSA HAB Performance Measure[3] of having the *most recent* laboratory result on file under 200 copies/mL.

VL Status	A	B	C	D	E	F	TOTAL
VL Suppression Rate	**69%** **73%**	**55%** **59%**	**55%** **60%**	**66%** **67%**	**59%** **60%**	**64%** **64%**	**60%** **63%**
Suppressed	46 (69%)	58 (55%)	53 (55%)	46 (66%)	62 (59%)	67 (64%)	332 (60%)
Mixed Status	8 (12%)	17 (16%)	12 (12%)	11 (16%)	9 (9%)	11 (10%)	68 (12%)
Unknown	5 (7%)	17 (16%)	19 (20%)	2 (3%)	15 (14%)	7 (7%)	65 (12%)
Unsuppressed	8 (12%)	13 (12%)	13 (13%)	11 (16%)	19 (18%)	20 (19%)	84 (15%)
NO INTERVENTION	6 (9%)	16 (15%)	10 (10%)	1 (1%)	11 (10%)	4 (4%)	48 (9%)
TOTALS	*67* *(100%)*	*105* *(100%)*	*97* *(100%)*	*70* *(100%)*	*105* *(100%)*	*105* *(100%)*	*549* *(100%)*

Across all primary care sites, the case management clients reviewed for these samples had a viral load suppression rate between 60-63%, depending on which estimate is used. 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.

Of particular interest in this review was the role of case management staff when a client received an unsuppressed laboratory result. For clients who were coded as "Unsuppressed," "Mixed Status," or "Unknown," the overall narrative of the client record was also reviewed to understand whether intervention from case management would have been appropriate and whether a CM staff did intervene to better coordinate care, encourage retention, or provide education on medication adherence. Overall, less than 10% of the sample (9%) was unsuppressed at some point during the review year *and* did not receive case management intervention when it would have been appropriate.

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[3] Health Resources and Services Administration HIV/AIDS Bureau. (2019, December). Performance Measure Portfolio. Retrieved from https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio

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
New to Care	6 (9%)	23 (22%)	5 (5%)	13 (19%)	6 (6%)	3 (3%)	56 (10%)
Lost to Care	6 (9%)	11 (10.5%)	12 (12%)	3 (4%)	9 (9%)	9 (9%)	50 (9%)
Re-engaged in Care	3 (4.5%)	6 (6%)	12 (12%)	2 (3%)	15 (14%)	14 (13%)	52 (10%)
New + Later Lost	3 (4.5%)	4 (4%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	8 (1%)
Re-engaged + Lost	0 (0%)	9 (8.5%)	5 (5%)	1 (1%)	2 (2%)	1 (1%)	18 (3%)
Coordination of Care	*94%* *(17 of 18)*	*70%* *(37 of 53)*	*65%* *(22 of 34)*	*85%* *(17 of 20)*	*94%* *(30 of 32)*	*78%* *(21 of 27)*	*78%* *(144 of 184)*
N/A	49 (73%)	52 (49%)	63 (65%)	50 (71%)	73 (69%)	78 (74%)	365 (67%)
TOTALS	*67*	*105*	*97*	*70*	*105*	*105*	*549*

Overall, 10% of the sample was considered New to Care, 9% was Lost to Care, and 10% was Re-engaged in Care. An additional 1% initiated services and were later lost, and 3% returned to care and were then later lost to care again within the same year. Notably, two agencies had a higher than average percentage of New to Care clients within their sample, with 22% of Agency B clients and 19% Agency D clients being new.

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. In the future, a more focused chart review sample of Outreach services may help to shed light on the benefits of this service category.

Every agency reviewed had policies and procedures in place for retention in care, as evidenced by both materials submitted as part of the Quality Management site visit and the percentage of New, Lost, and Re-engaged clients who received some type of retention in care service or service attempt. 78% of the clients within the sample who would have been subject to Coordination of Care services were contacted or assisted by staff in an effort to retain them in care. Some agencies had remarkably high Coordination of Care rates, at 94%.

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 ABUSE (history or active)

Any diagnosis of a mental health disorder (MH) or substance abuse issue (SA) was recorded in the chart review tool, including a history of mental illness or substance abuse. All Electronic Medical Records include some variation of a “Problem List” template. This list was often a good source of information for MH and SA 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 substance abuse, 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 SA issues. Any conditions other than alcohol abuse, other substance abuse, 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.

	A	B	C	D	E	F	G	TOTAL
% of sample w/ MH or SA issue	**51%**	**45%**	**49%**	**39%**	**53%**	**61%**	**80%**	53% (323 of 609)
Alcohol abuse/ dependence	9 (13%)	8 (8%)	7 (7%)	1 (1%)	4 (4%)	9 (9%)	6 (10%)	44 (7%)
Other Substance Abuse/ Dependence	7 (10%)	15 (14%)	19 (20%)	11 (16%)	38 (36%)	27 (26%)	13 (22%)	130 (21%)
Depression	15 (22%)	34 (32%)	24 (25%)	9 (13%)	22 (21%)	41 (39%)	12 (20%)	157 (26%)
Bipolar Disorder	6 (9%)	10 (10%)	7 (7%)	6 (9%)	6 (6%)	5 (5%)	9 (15%)	49 (8%)
Anxiety	13 (19%)	11 (10%)	17 (18%)	5 (7%)	5 (5%)	15 (14%)	6 (10%)	72 (12%)
Schizophrenia	3 (4%)	2 (2%)	1 (1%)	0 (0%)	7 (7%)	1 (1%)	2 (3%)	16 (3%)
Other	12 (18%)	16 (15%)	27 (28%)	6 (9%)	9 (9%)	16 (15%)	32 (53%)	118 (19%)
TOTALS	*67*	*105*	*97*	*70*	*105*	*105*	*60*	*609*

Overall, 53% 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 SA issue is an eligibility criteria.

MENTAL HEALTH & SUBSTANCE ABUSE REFERRALS

For clients with an *active* diagnosis of a mental health or substance abuse issue, the chart abstractor recorded if they were referred or already engaged in MH/SA 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%.

Received MH Referral?	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**TOTAL**
N/A	39 (58%)	64 (61%)	54 (56%)	46 (66%)	68 (65%)	50 (48%)	7 (12%)	328 (54%)
Yes	25 (37%)	28 (27%)	38 (39%)	24 (34%)	35 (33%)	52 (50%)	53 (88%)	255 (42%)
No	3 (5%)	13 (12%)	5 (5%)	0 (0%)	2 (2%)	3 (3%)	0 (0%)	26 (4%)
TOTALS	*67* *(100%)*	*105* *(100%)*	*97* *(100%)*	*70* *(100%)*	*105* *(100%)*	*105* *(100%)*	*60* *(100%)*	*609* *(100%)*

Overall, 54% of the sample would not have been appropriate for a MH or SA referral based on the information available in their medical record. An additional 42% either did receive a referral or were already engaged in treatment and 4% did not receive a referral. This means that 91% of the sample (or 255 out of 281 individuals) who should have received a referral did receive one, according to their medical chart.

> *91% of the sample with active MH or SA symptoms was either referred for further counseling or treatment or already engaged in services.*

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 31% and 23% prevalence within the sample, respectively. Insomnia was the most common co-occurring condition that was coded in the "Other" category.

	A	B	C	D	E	F	TOTAL
Opportunistic Infection	2	2	2	1	4	3	14
	(3%)	(2%)	(2%)	(1%)	(4%)	(3%)	(3%)
STI	11	38	37	28	23	32	169
	(16%)	(36%)	(38%)	(40%)	(22%)	(30%)	(31%)
Diabetes	11	12	4	4	20	8	59
	(16%)	(11%)	(4%)	(6%)	(19%)	(8%)	(11%)
Cancer	0	0	0	0	4	1	5
	(0%)	(0%)	(0%)	(0%)	(4%)	(1%)	(1%)
Hepatitis	4	24	6	4	17	7	62
	(6%)	(23%)	(6%)	(6%)	(16%)	(7%)	(11%)
Hypertension	12	18	25	13	28	29	125
	(18%)	(17%)	(26%)	(19%)	(27%)	(28%)	(23%)
Other	14	15	15	18	21	6	89
	(21%)	(14%)	(15%)	(26%)	(20%)	(6%)	(16%)
TOTALS	*67*	*105*	*97*	*70*	*105*	*105*	*549*

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. 4% of the sample reported experiencing some other type of social issue, the most common of which being a disclosed history of childhood sexual abuse.

	A	B	C	D	E	F	G	TOTAL
Homelessness or housing-related issues	4 (6%)	11 (10%)	9 (9%)	11 (16%)	8 (8%)	11 (10%)	6 (10%)	60 (10%)
Pregnancy or pregnancy-related issues	2 (3%)	0 (0%)	1 (1%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	4 (1%)
Recently released	0 (0%)	5 (5%)	2 (2%)	5 (7%)	5 (5%)	6 (6%)	5 (8%)	28 (5%)
Intimate Partner Violence	3 (4%)	2 (2%)	0 (0%)	2 (3%)	2 (2%)	3 (3%)	2 (3%)	14 (2%)
Other	3 (4%)	2 (2%)	3 (3%)	3 (4%)	5 (5%)	7 (7%)	2 (3%)	25 (4%)
TOTALS	*67*	*105*	*97*	*70*	*105*	*105*	*60*	*609*

CASE MANAGEMENT ROLE DELEGATION

One area of interest for the Ryan White Grant Administration Quality Management team is to quantify and better help address the workflow and role delegation of medical case management and non-medical case management staff within the Ryan White system of care. According to the service category definitions and funding structure, care should be taken to ensure that clients are assigned to work with case management staff according to their level of need.

Individuals who have higher, more intensive levels of need that interfere with their ability to stay successful in HIV treatment should be assigned to work with a licensed social worker for medical case management services. Individuals who have lower, more intermittent need that could be assisted through straight forward referral and follow-up (versus ongoing management) are more appropriate for non-medical case management services by Service Linkage Workers. Client needs and acuity levels should be assessed at intake and monitored throughout regular periods in the year to continuously evaluate what services and staff would be the best "fit" for a client's individual needs. In this way, resources can be appropriately allocated within the system of care and clients can be assigned to work with someone who can best meet their needs.

For these reasons, the chart abstractor documented what type of case manager each client worked with (a Medical Case Manager or Service Linkage Worker) and whether that client met the specified eligibility criteria for medical case management. It was also not uncommon for clients to work with both a Medical Case Manager *and* Service Linkage Worker within the same year, either because their level of need changed or to ensure that a client's issues were addressed in a timely manner, regardless of whether the most appropriate staff member was available in the clinic.

	A	B	C	D	E	F	TOTAL
Worked with MCM	51 (76%)	67 (64%)	70 (72%)	34 (49%)	16 (15%)	47 (45%)	285 (52%)
Met criteria for MCM	*37* (73%)	*34* (51%)	*68* (97%)	*30* (88%)	*16* (100%)	*44* (94%)	*229* *(80%)*
Worked primarily with SLW	17 (25%)	48 (46%)	62 (64%)	40 (57%)	96 (91%)	59 (56%)	322 (59%)
Met criteria for MCM	*3* (18%)	*11* (23%)	*8* (13%)	*7* (18%)	*16* (18%)	*11* (19%)	*56* *(17%)*
TOTALS	*67*	*105*	*97*	*70*	*105*	*105*	*549*

52% of the sample worked with a Medical Case Manager (licensed social worker) at any point within the review year and 80% of those clearly met the eligibility criteria for medical case management. An additional 7% of the sample was marked as "unknown" for whether they met the medical case management eligibility criteria, as a way for the chart abstractor to acknowledge that there may be more detail to the client's case than the information available in the medical record.

59% of the sample *primarily* worked with a Service Linkage Worker (SLW) within the review year, meaning that they either only worked with an SLW, or all of their interactions except for one were with an SLW. Of those, 17% had some information available in their medical record indicating that they technically met the criteria for medical case management and may have been considered more appropriate to work with a licensed social worker.

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
0	18 (27%)	28 (27%)	23 (24%)	2 (3%)	10 (10%)	7 (7%)	13 (22%)	101 (17%)
1	27 (40%)	34 (32%)	14 (14%)	31 (44%)	3 (3%)	38 (36%)	15 (25%)	162 (27%)
2	6 (9%)	2 (2%)	0 (0%)	1 (1%)	1 (1%)	2 (2%)	4 (7%)	16 (3%)
N/A	16 (24%)	41 (39%)	60 (62%)	36 (51%)	91 (87%)	58 (55%)	28 (47%)	330 (54%)
Completion Rate	**97%**	**70%**	**46%**	**100%**	**93%**	**91%**	**91%**	94% (570 out of 609)
TOTALS	*67*	*105*	*97*	*70*	*105*	*105*	*60*	*609*

The date of each assessment was recorded in the chart abstraction tool. 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 in the previous section, 48% of the sample did not work with a Medical Case Manager within the year. An additional 6% were served by a Medical Case Manager for a one-time, immediate need which was justified by staffing needs, most often an ADAP application or re-certification issue. 17% of the sample received zero comprehensive assessments, 27% received one, and 3% received two.

Completion Rate for this analysis was defined as the percentage of eligible medical case management clients who were assessed *at least once* throughout the year *or* had a documented reason for why they did not receive a comprehensive assessment (most often this was because the client declined or because they were no longer receiving medical case management services), *or*¸ they had evidence of an assessment just outside of the chart review dates. By this calculation, 94% of clients who should have received an assessment within the year did indeed receive one.

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, the date of 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
0	25 (37%)	32 (30%)	32 (33%)	4 (6%)	10 (10%)	7 (7%)	20 (33%)	130 (22%)
1	22 (33%)	30 (29%)	5 (5%)	29 (41%)	3 (3%)	38 (36%)	11 (18%)	138 (23%)
2	4 (6%)	2 (2%)	0 (0%)	1 (1%)	1 (1%)	2 (2%)	1 (2%)	11 (2%)
N/A	16 (24%)	41 (39%)	60 (62%)	36 (61%)	91 (87%)	58 (55%)	28 (47%)	330 (54%)
Completion Rate	**73%**	**64%**	**22%**	**94%**	**93%**	**91%**	**72%**	**87%** (527 out of 609) **11%** (29 out of 279)
TOTALS	*67 (100%)*	*105 (100%)*	*97 (100%)*	*70 (100%)*	*105 (100%)*	*105 (100%)*	*60 (100%)*	*609 (100%)*

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. One common reason for this, as documented frequently in the client medical records, is that clients would often decline to continue on to complete the service plan, given the amount of time they had already spent in the clinic for the lengthy comprehensive assessment interview, in addition to whatever medical appointment they may have attended on that day.

Completion rates were calculated in two different ways. The first calculation, in blue, is the more liberal analysis that is consistent with the manner used to calculate the completion rate for comprehensive assessment. It is the percentage of eligible clients who received *at least one* service plan throughout the year *or* had a documented reason for why they did not complete the service plan *or* they had evidence of a completed service plan just outside of the review dates. By this calculation, 87% of clients who should have received a service plan within the year did indeed receive one.

The second, more conservative measurement in red is the more universally accepted standard for care planning in Ryan White Case Management Services, consistent with the HAB HRSA Performance Measure for Case Management[4]. This is the number of clients who were receiving case management services within the year and received at least two service plans within the year, excluding those had a documented reason for not completing a second care plan, such as only being enrolled in case management for only some of the year.

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[4] Health Resources and Services Administration HIV/AIDS Bureau. (2019, December). Performance Measure Portfolio: MCM Measures. Retrieved from https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/mcmmeasures.pdf

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**
0	7 (10%)	6 (6%)	15 (15%)	2 (2%)	16 (15%)	14 (13%)	60 (11%)
1	10 (15%)	28 (27%)	37 (38%)	37 (53%)	49 (47%)	41 (39%)	202 (37%)
2	0 (0%)	1 (1%)	0 (0%)	1 (1%)	5 (5%)	4 (4%)	11 (2%)
N/A	50 (75%)	70 (67%)	45 (46%)	30 (43%)	35 (33%)	46 (44%)	276 (50%)
Completion rate	**94%**	**97%**	**77%**	**98%**	**86%**	**97%**	**91%** (248 out of 273)
TOTALS	*67* *(100%)*	*105* *(100%)*	*97* *(100%)*	*70* *(100%)*	*105* *(100%)*	*105* *(100%)*	*549* *(100%)*

Dates of any brief assessments were recorded, along with any justification of why an assessment was not completed if one would have been expected. 50% of the sample would not been applicable for a brief assessment, as they did not receive services from a Non-Medical Case Manager. 11% of the sample received zero brief assessments, 37% received one, and 2% received two.

Completion rates represent the percentage of eligible clients who received *at least one* assessment within the review year *or* had a documented reason as to why one was not completed *or* had evidence of a completed assessment just outside of the review period.

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 top five most frequently assessed needs were: 1) Medical/Clinical, 2) Dental Care, 3) Vision Care, 4) Transportation, and 5) Mental Health. 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. For example, it was much more common for "Dental Care" to be identified as a need at agencies who had dental care co-located or easily available within their organization. Anecdotally, some case managers reported that they automatically checked "Medical/Clinical" 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	Count	Percentage %
Medical/Clinical	141	37%
Dental Care	123	32%
Vision Care	108	28%
Transportation	99	26%
Mental Health	95	25%
Insurance Benefits	85	22%
Medication Adherence	79	21%
Housing/Living Situation	66	17%
Substance/Alcohol Use	65	17%
HIV Education/Prevention	50	13%
Support System	34	9%
Employment/Income	34	9%
HIV-Related Legal	31	8%
Self-Efficacy	30	8%
Basic Necessities/Life Skills	29	8%
Nutrition/Food Pantry	22	6%
Family Planning/Safer Sex	15	4%
Financial Assistance	14	4%
Abuse History	12	3%
Cultural/Linguistic	9	2%
General Education/Vocation	9	2%
Vaccination	8	2%
Hearing Care	8	2%
Home Care Needs	5	1%
Client Strengths	4	1%
Child Care/Guardianship	2	1%
Other	2	1%
		Out of 384 assessments

Conclusion

The 2018-2019 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 top three most common co-occurring conditions were: Sexually Transmitted Infections (31%), Depression (26%), and Hypertension (23%). Diabetes was also relatively common (11%) and it has been suggested that providing overview information on nutrition counseling and diabetes management may be a useful topic for future frontline case management trainings. In addition, 53% of the overall sample had a history or active diagnosis of a mental health or substance abuse issue. 10% of the sample was homeless or unstably housed. The prevalence of these complex co-morbidities further 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 (39%) of the clients in the sample had at least three HIV-related primary care appointments within the review year. While the measurement for Viral Load Suppression changed from last year's chart review, there was a marked improvement in overall VL suppression from 43% to this year's 60%. Case Management staff demonstrated a high level of coordination of care in many areas. For example, 91% 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. 78% 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. And finally, when a client was found to be virally unsuppressed through a laboratory test, case management staff were often involved to follow-up with clients and provide medication adherence counseling. Less than 10% of sample was found to be virally unsuppressed at some time throughout the year and did not receive attention and intervention from case management staff.

Case Management staff demonstrated high levels of coordination of care:

- 91% MH and SA referral rate

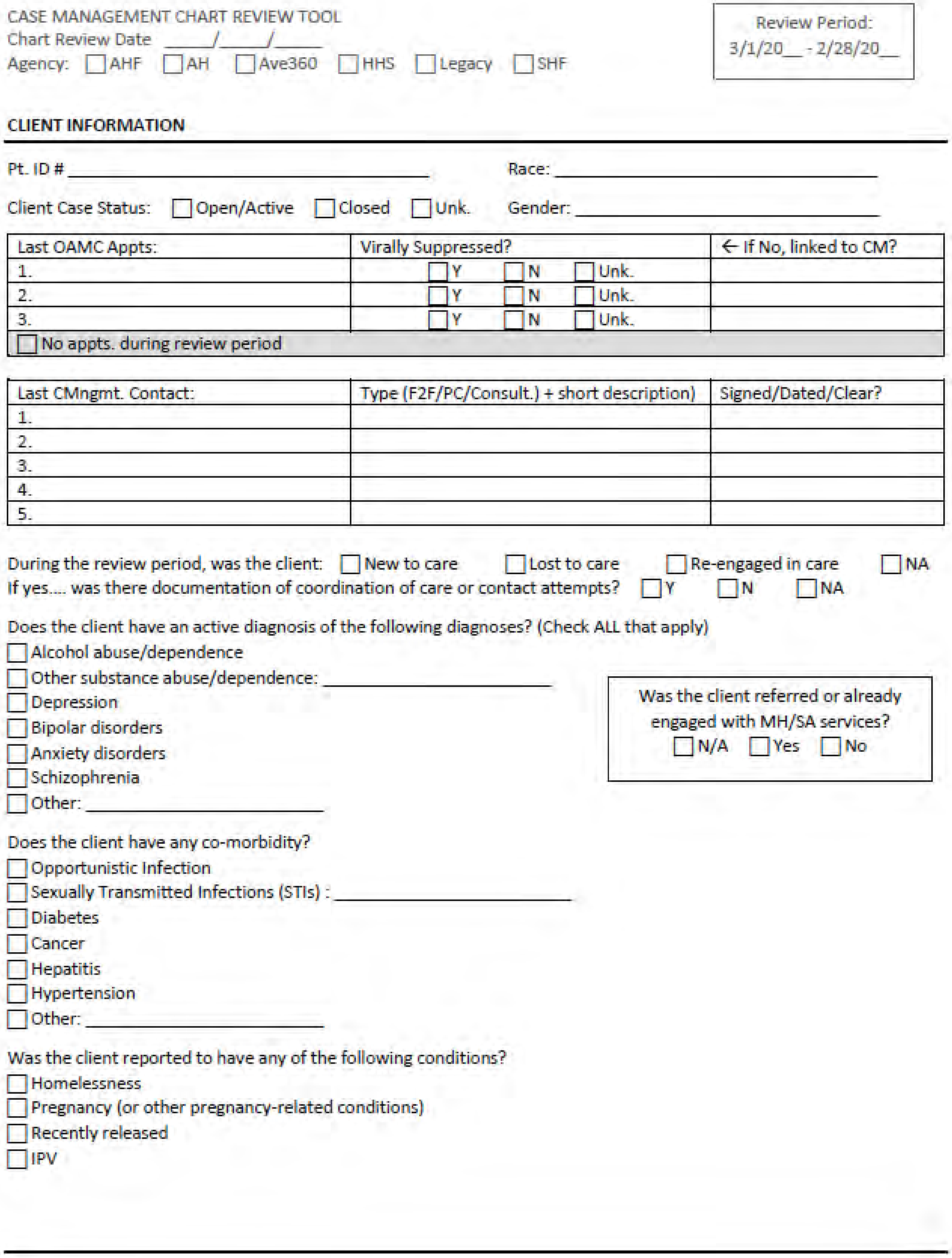
- 78% of New, Lost, or Returning to Care clients were assisted by CM

- <10% of sample was unsuppressed without intervention

The review also highlighted that there are still many opportunities for refinement in case management workflow and service provision. Termination planning and review for case closure were inconsistently practiced across agencies. The discrepancy between the completion rate for one assessment versus two assessments per year is striking. This indicates that, as a case management system, we are good at initiating services, but need to dedicate much more attention to following clients throughout their care. It is quite possible that the 11% performance rate of 2 care plans within a year for medical case management clients is artificially low if many of those clients could be considered "closed" for case management and excluded from the calculation. However, without proper case closure documentation in the medical chart and, worse, without communication to the client to follow-up with them or manage service expectations, those cases are considered "open" for all intents and purposes.

This lack of follow-through is further evidenced in the frequency of contact with a case manager. More than half (56%) of the sample had three or fewer interactions with the case manager. If the ideal standard is for a client to be formally assessed at least twice throughout the year to discuss their history, present concerns, barriers, and goals, with follow-through in between those formal sit-downs to work through the issues identified in the care plan, it leaves room to wonder how clients can be adequately served. Further training and capacity building in the areas of assessment and interview techniques, as well as continuing to refine case management role delegation, may help improve quality in these areas.

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

	MOST RECENT ASSESSMENT TYPE (circle one) Comprehensive Brief					NEXT MOST RECENT ASSESSMENT TYPE (circle one) Comprehensive Brief				
Domain	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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Linkage to Care for Newly Enrolled Clients
Performance Improvement Activity (PIA)
For Case Management Supervisors
2018-2019 (and beyond)

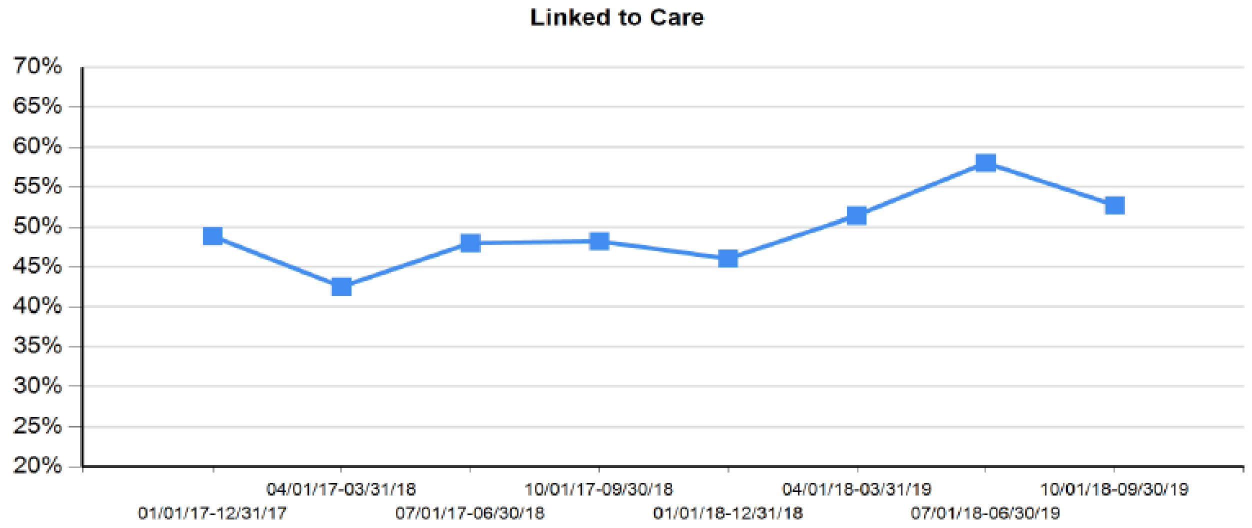
Key Highlights

- Following clients through their first year of care in a new clinic may be considered an effective intervention for HIV treatment outcomes.
- Clinic workflows should be optimized to ensure a patient-centered experience and effective treatment monitoring. It was surprising to find that many patients were not automatically prompted to schedule a follow-up visit, or asked for their input on what dates and times would work best for them, or that many did not have a recent (within 6 months) CD4 and VL lab on file.
- While HIV treatment management is down trending towards two primary care appointments per year, the findings from this activity suggest that new clients (without distinguishing between newly diagnosed, new to treatment, or just new to your clinic) may still benefit from having appointments scheduled every 3 months.

Project Description

Linkage to Care (L2C) is one important indicator used to predict treatment outcomes for new patients in HIV management. L2C performance measures vary across local and regional jurisdictions. The HRSA HAB Performance Measure Portfolio includes a Systems-Level Linkage to HIV Medical Care measure that is defined as the percentage of patients who attend a routine HIV medical care visit within 1 month of diagnosis. The Houston Ryan White Part A system includes three different Linked to Care measures for monitoring as part of Clinical Quality Improvement activities, one of which provided the basis for this Case Management Performance Improvement Activity.

This “Linked to Care 1” measurement monitors the number of newly enrolled uninsured clients who had at least one medical visit in each of the 4-month periods of the measurement year. This measure has hovered around 50% for the last couple years.



Deeper analysis was desired to better understand patients' experience in their first year of care as newly enrolled clients, particularly given that the Ryan White case management service models include Service Linkage Workers and intensive Medical Case Management aimed at new patients. By engaging Case Management (CM) Supervisors to prompt their staff to take a close look at newly enrolled clients, the intent of this PIA was to improve L2C performance.

For the purposes of this activity, new clients were defined as:

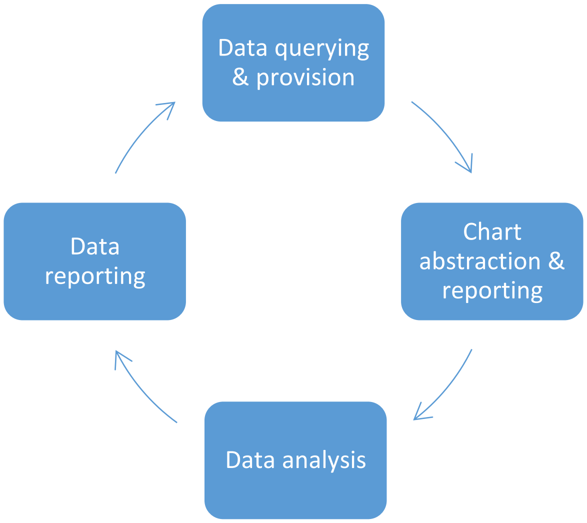
- Newly enrolled clients during the specified three-month period with at least one medical visit
- Excluding those who are insured and who are virally suppressed (<200 copies/ml)

With this definition in mind, it is important to understand that this activity is not necessarily aimed at understanding newly diagnosed patients or even new-to-treatment patients, though these populations may be captured in the data sets.

Each phase of the PIA is designed to repeat three times for a total of four quarters of data reporting. These four "cohorts," as they are referred to, are data sets for clients who were considered newly enrolled for the following time frames:

- Quarter/Cohort 1: March-May 2018
- Quarter/Cohort 2: June-August 2018
- Quarter/Cohort 3: September-November 2018
- Quarter/Cohort 4: December 2018-February 2019

Each quarter, the CPCDMS data base was queried by the Ryan White Grant Administration epidemiologist to provide a client list for CM Supervisors of their newly enrolled clients for that 3-month period. Supervisors were then instructed to conduct a chart review for each client on their list to complete each relevant data field. Results were then returned to RWGA Quality Management staff for analysis, after which the results were compiled and reported out to each agency for reflection and discussion, before repeating.



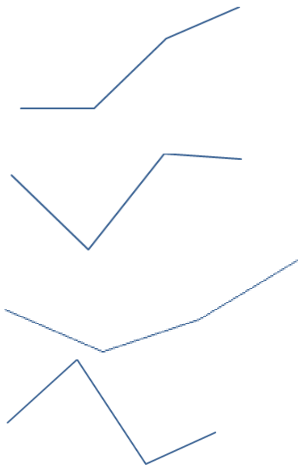
Phase 1 of PIA: Quarterly Linkage to Care

The first phase of the L2C PIA aimed to monitor performance of case managers for successful linkage to care of newly enrolled clients seeking HIV primary care treatment. For this phase of the activity, successful "linkage" was defined as the presence of an initial HIV-related primary care appointment during the specified time range, followed by attendance at a follow-up appointment during the next 3-month period.

Each quarter, CM Supervisors were provided a list of new clients who enrolled during the specified time frame. They were instructed to return the list in the following quarter, reviewing the patient chart to determine: 1) whether they were scheduled for a "next" primary care appointment in a following quarter, 2) whether they attended that next appointment, 3) whether they were enrolled or receiving case management services, 4) and whether they were virally suppressed. This activity was repeated for four quarters to measure trends and improvement.

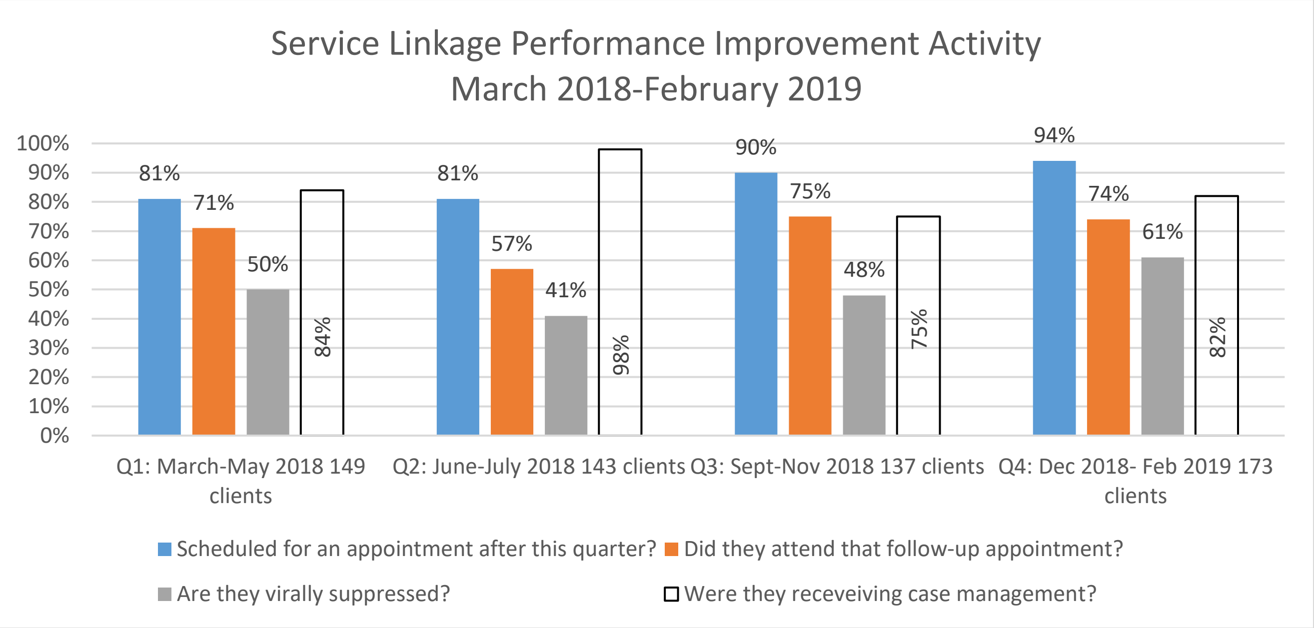
	Q1: March-May 2018 149 clients	Q2: June-July 2018 143 clients	Q3: Sept-Nov 2018 137 clients	Q4: Dec 2018-Feb 2019 173 clients
Scheduled for an appointment in the next quarter?	81%	81%	90%	94%
Did they attend that follow-up appointment?	71%	57%	75%	74%
Are they virally suppressed?	50%	41%	48%	61%
Are they receiving case management?	84%	98%	75%	82%

Linear progression



While performance did not improve linearly throughout this project phase, performance certainly had a marked improvement from the first quarter to the last. For example, 81% of clients from the first cohort at the beginning of the study were scheduled for a follow-up appointment. By the last quarter, 94% of the final cohort had been scheduled for a follow-up appointment. Similarly, viral load suppression increased from 50% to 61%.

These findings suggest that by virtue of providing focused attention to newly enrolled clients and assigning responsibility to particular staff to query patient health and attendance records and follow-up, outcomes can improve.


Service Linkage Performance Improvement Activity
March 2018-February 2019

Phase 2 of PIA: Retrospective "Second Look" Cohort Study

Following the completion of the first performance monitoring phase of the PIA for Year 1, the second year of the PIA initiated a retrospective cohort study. This phase of the PIA is currently ongoing, with two cohorts worth of data available. The purpose of this phase is to take a "second look" at each original cohort, one year later, to further understand what their first year in care has been like.

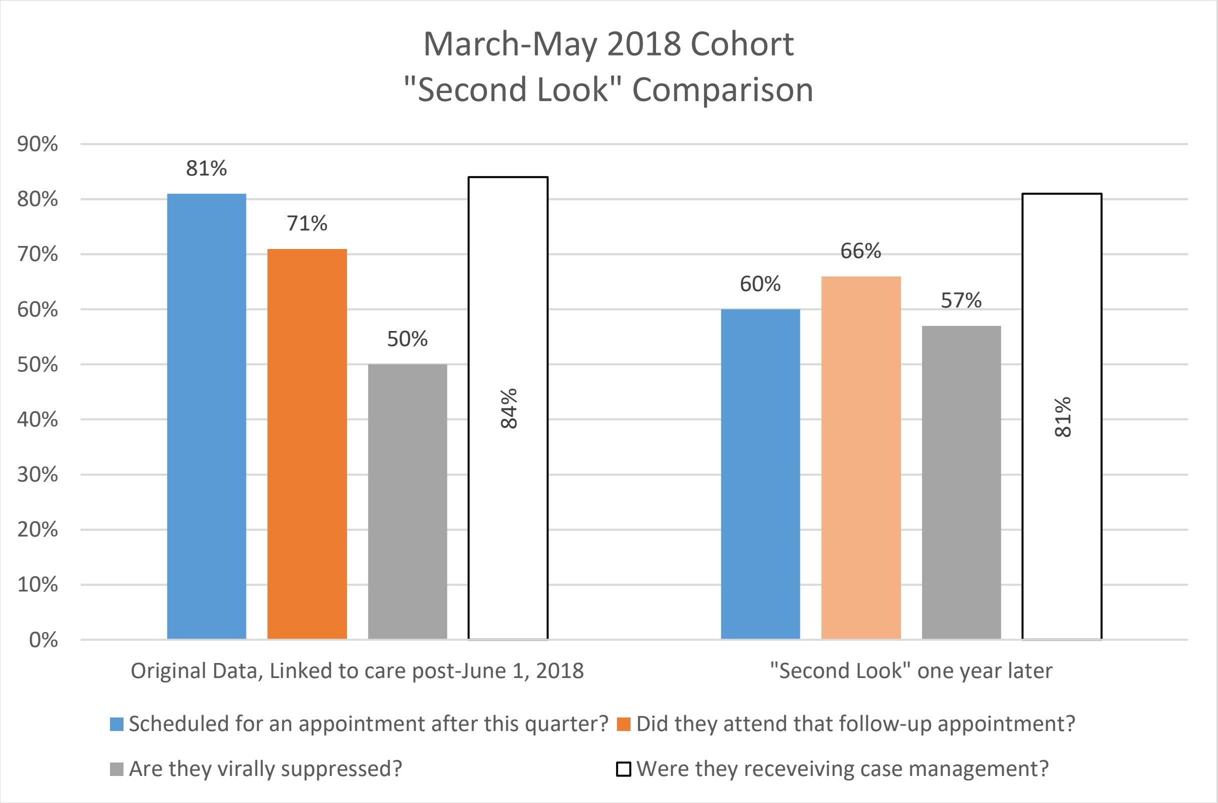
CM Supervisors were prompted to conduct a chart review for each of the clients on their original cohort list, identifying the following items: 1) Did the client have an HIV primary care appointment scheduled in each of the following quarters of their last year in care? 2) Have they been scheduled for a post-last quarter appointment, indicating they would be successfully "linked" to a second year of treatment in that facility? 3) When was their last laboratory CD4 and VL test performed and were they virally supressed at that point in time? And finally, 4) were they enrolled in case management services during the year and, if so, how many case management encounters did they have?

For the purposes of this phase of the activity, attendance at a follow-up appointment from the first point in time will be compared to presence of lab work in the last 6 months.

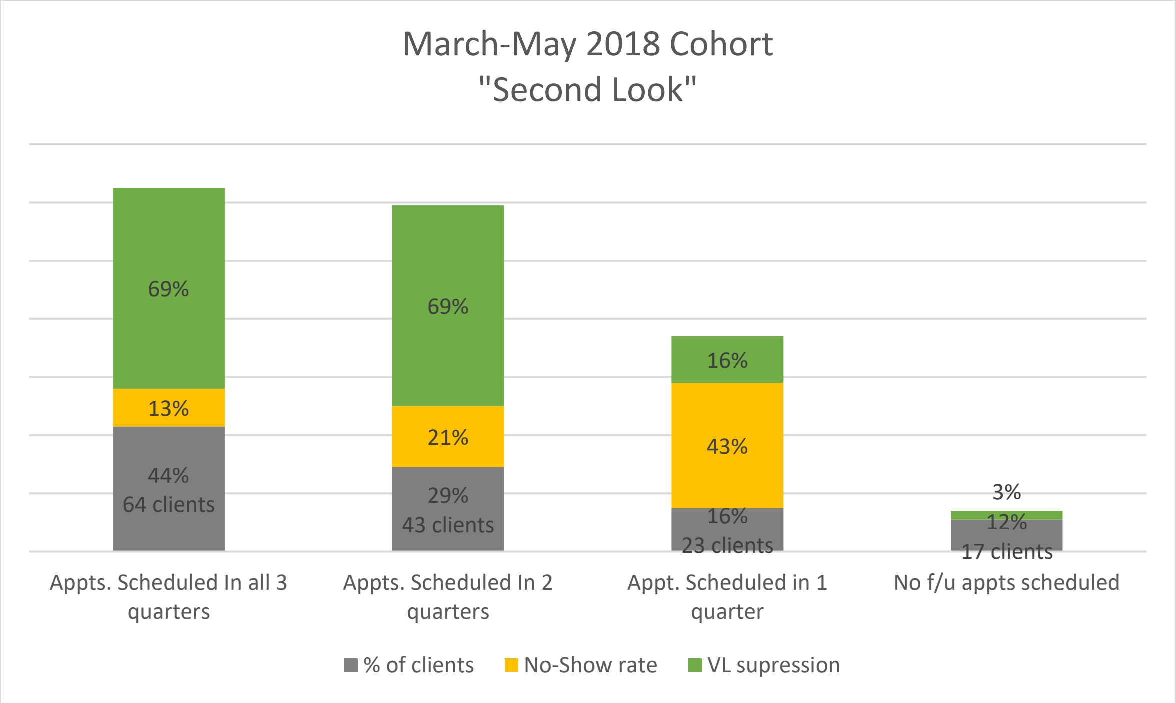
As with Phase 1, Phase 2 is expected to take one year to complete. To date, two cohorts have been re-examined for their second look.

Cohort 1: March-May 2018

The following comparison is of the March-May 2018 Cohorts June 2018 data and their June 2019 status. Data was returned for 147 of the original 149 clients.



By June 2019, 60% of the original cohort had been scheduled for an appointment sometime after June 1st, 2019, indicating they were still engaged in care. 66% have had lab work completed in the last 6 months. 57% were known to be virally supressed in the last 6 months. 81% had received case management services over the last year, with an average of **5** encounters.



Client outcomes were also examined to understand whether the number of scheduled appointments in the year had an impact on viral load suppression. 44% of clients were scheduled for an HIV primary care appointment in each of the following three quarters examined, while 29% had an appointment scheduled in two of the quarters, 16% with an appointment in just 1 quarter, and 12% with no follow-up appointments scheduled. It is of note that of the 17 clients who were not followed-up with at all, 1 appeared to have established care at a different Ryan White clinic, 1 was deceased, 1 was no longer in CPCDMS, and 14 had no further appointments in the RW-A system.

Clients who were scheduled for either three or two appointments had the same VL suppression rate at 69%, while clients with two appointments scheduled had a 43% suppression rate.

No-show rates were also examined. Clients with 3 follow-up appointments (one in each of the next quarters) had a 13% no-show rate and clients with 2 scheduled appointments had a 21% no-show rate. 43% of clients who were scheduled for one appointment did not attend that appointment.

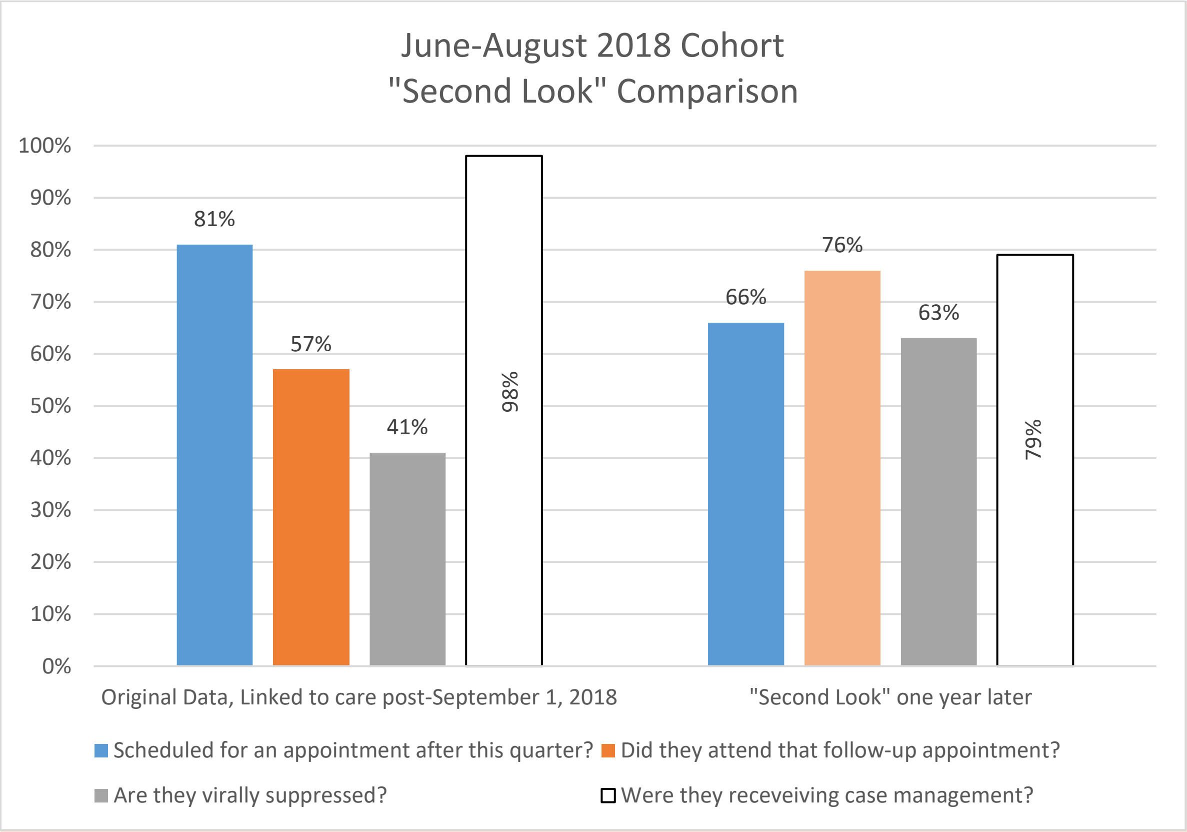
While these findings suggest that scheduling two appointments per year may be sufficient for clients to achieve the ultimate indicator of viral load suppression, even in their first year of care, more analysis was needed to understand the impact of no-show and cancellation rates.

	Number/Percentage	VL Suppression Rate
3 appointments attended	44 (30%)	84%
2 appointments attended	45 (31%)	87%
1 appointment attended	30 (20%)	23%
0 appointments attended	28 (19%)	12%

When actual number of appointments attended was analyzed, clients who attended 2 appointments had the highest viral load suppression rate at 87%, followed closely by patients who attended 3 appointments at 84%. There are likely many confounding variables and factors that would influence why patients with less appointments achieve viral load suppression (slightly) more often. For example, long-term survivors who have a wealth of experience in managing their care may be more likely to opt for fewer appointments. Providers may make the decision to schedule and encourage more appointments to monitor patients who are having trouble with treatment adherence.

Cohort 2: June-August 2018

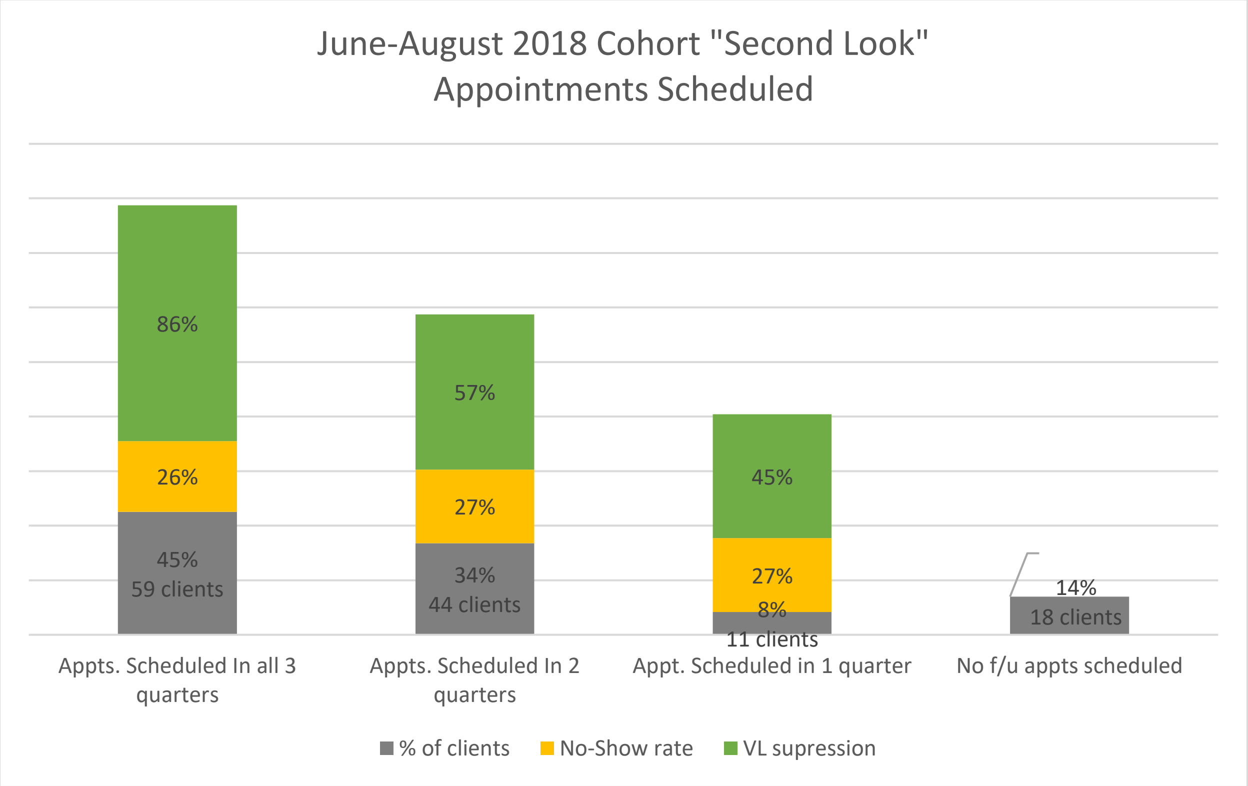
Most recently, this activity was repeated for Cohort 2, the June-August 2018 set of clients. Data was returned for 131 of the original 143 clients.



By October 2019, 66% of the original cohort had been scheduled for an appointment sometime after September 1st, 2019. 76% have had lab work completed in the last 6 months. 63% were known to be virally supressed in the last 6 months. This marks an improvement on all clinical measures from the first cohort.

79% had received case management services over the last year, with an average of **5** encounters. It is also noteworthy that the less appointments a patient was scheduled for, the more number of case management encounters they averaged. This suggests that case management staff may have been attempting to engage and retain clients who were less likely to be successfully linked to care.

Just like the first cohort, clients outcomes were analyzed based on number of scheduled appointments. The results were dissimilar to the first cohort.



45% of clients were scheduled for a primary care appointment in each of the three quarters examined, while 34% had an appointment scheduled in two of the quarters, 8% with an appointment in just 1 quarter, and 14% with no follow-up appointments scheduled.

Unlike the first cohort, clients scheduled for three additional appointments had the highest VL suppression rate at 86%, while clients with two appointments scheduled had a 57% suppression rate.

No-show rates were similar across groups, with about a quarter of appointments resulting in “no-show” or cancellations, regardless of how many they were scheduled.

When clients from this cohort were analyzed by number of appointments actually attended, the effect of appointment frequency was even more pronounced. Clients who attended all three follow-up appointments achieved a 93% VL suppressions rate, followed by clients attending 2 appointments at 74%.

	Number/Percentage	VL Suppression Rate
3 appointments attended	42 (32%)	93%
2 appointments attended	35 (27%)	74%
1 appointment attended	23 (18%	52%
0 appointments attended	31 (24%)	16%

Conclusions

While this PIA is only 1.5 years of the way completed through its projected 2 years of study, there have been a few key findings thus far.

First, the theory that continuous monitoring of newly enrolled clients would improve treatment outcomes seems to have been correct, as is consistent with quality improvement and management frameworks. While performance improvement for the first phase of the PIA was not linear, performance did improve from the first cohort to the last. Anecdotally, the CM supervisors have reported that providing a list of new clients for review each quarter is a helpful activity. As a result, RWGA has continued to provide these cohort lists at the agencies' request even though that phase of the PIA has concluded.

Second, this quarterly prompt to conduct a focused chart review has revealed that many clinic practices that were assumed to be occurring as part of routine HIV care were indeed not. For example, the CM Supervisors were surprised to learn that only 81% of clients in the first cohort had been scheduled for a follow-up appointment, a process which should be automatic and consistent. This revelation may have been what prompted the continuous improvement for this measure; scheduling for a follow-up appointment was the only measurement that had a clear linear progression towards improvement. In addition, participating in this activity highlighted a gap in clinic workflow in the way of laboratory testing, which is a cornerstone of HIV treatment and management. It was not uncommon for clients to be missing a recent (within the last 6 months) CD4 and VL lab result, even if they had been regularly attending face-to-face provider appointments. Clinics tend to have a different workflow for scheduling provider and lab appointments. Further study, possibly including internal environmental walk-through audits, should be conducted to optimize a patient-centered experience and to understand why so many clients do not regularly have HIV labs conducted.

Finally, the results of this PIA suggest that scheduling HIV-related primary care appointments every three months may be optimal as compared to the down trending preference for 2-3 appointments per year, particularly for new clients. While the second phase of this activity is still ongoing, results from the first two retrospective cohort studies suggest that not only are 3 follow-up appointments correlated with higher viral load suppressions rates, but scheduling patients for an appointment every quarter can help to ensure that they make it to at least a few appointments each year, given the cancellation and no-show occurrence.

Open access Protocol

BMJ Open

Telehealth and texting intervention to improve HIV care engagement, mental health and substance use outcomes in youth living with HIV: a pilot feasibility and acceptability study protocol

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ABSTRACT

Introduction Youth and young adults living with HIV (YLWH) experience worse clinical outcomes than adults and high rates of behavioural health challenges that impact their engagement in care and adherence to antiretroviral therapy. This study in the San Francisco Bay area aims to evaluate the feasibility, acceptability and preliminary clinical outcomes of a 12-session telehealth counselling series provided to 80 YLWH, including education, motivational enhancement and problem-solving around HIV care, mental health, substance use and other challenges. Findings will provide information about benefits and challenges of telehealth counselling for YLWH and will guide the development of new technology-based strategies for care.

Methods and analysis The Youth to Telehealth and Text to Improve Engagement in Care study is a pilot randomised, crossover trial examining the feasibility and acceptability of a telehealth counselling intervention consisting of twelve 20–30 min weekly sessions focused on identifying and problem-solving around barriers to HIV care access and adherence and on addressing mental health, substance use and/or other issues. Participants also receive text messages for check-ins, appointment reminders and to improve engagement. Participants complete quantitative online surveys at baseline, 4 and 8 months and qualitative exit interviews. Clinical outcomes, including plasma HIV RNA and CD4+ cell count, are collected from medical records. Study staff will explore outcomes of the intervention using quantitative and qualitative methods.

Ethics and dissemination This study and its protocols have been approved by the University of California, San Francisco (UCSF) Institutional Review Board. Study staff will work with the UCSF Center for AIDS Prevention Studies' Community Engagement Core and the Youth Advisory Panel to disseminate results to the community, participants and the academic community.

Trial registration NCT03681145.

Strengths and limitations of this study

- The use of iterative refinement of the intervention manual throughout this pilot study increases the study's potential impact and acceptability among participants.
- The study's counselling intervention is significant in its integrated HIV and behavioural health focus, which is tailored to the participant's baseline HIV knowledge, mental health status and substance use.
- The use of video chat and text messaging modalities for delivery of HIV engagement, mental health and substance use counselling with youth living with HIV is important, reduces the time burden to the clinician and patient and challenges the current delivery of healthcare.
- By examining the acceptability of a fully online versus hybrid in-person online session delivery, we will be able to determine if this intervention can be offered completely remotely, which will in turn increase the geographic reach for the delivery of this intervention.
- This pilot study is limited due to its small sample size, and the data generated from this study may not be generalisable to older individuals and those not living in the San Francisco Bay Area.

BACKGROUND

Youth and young adults aged 18–29 years living with HIV (YLWH) have unique challenges with HIV diagnosis, access and maintenance of care. In 2016, in the USA, youth aged 13–24 years accounted for about 21% of all new HIV infections.[1] Among those aged 13–29 years and living with HIV, only 41% were estimated to be aware of their HIV status. In 2014, of those diagnosed with HIV, only 62% accessed HIV medical care within the first year; of those, 43% were retained in HIV care, and 54% had a suppressed HIV viral load.[2] Access to care and antiretroviral therapy (ART) is crucial for the health of YLWH; high levels of ART adherence is critical for attaining HIV treatment goals including sustaining suppressed HIV viral load, decreasing risk of developing drug-resistant strains of HIV, reducing the risk of HIV transmission to others and improving overall health.[3–5]

Mental health and substance use challenges are prevalent in YLWH, though few studies have been conducted on behavioural health issues in YLWH. One study found that 18% of YLWH who were in care had clinically significant psychological symptoms such as depression or anxiety.[6] Another study of 1706 YLWH found that 42.6% reported mental health concerns at a clinically significant level. Of those reporting these symptoms, only 39.7% reported receiving mental healthcare services in the past year, and 21.9% reported taking medications for mental health conditions.[7] Additionally, in one sample of 12- to 26-year-olds living with HIV, 32% used tobacco, 27% used marijuana, 21% used alcohol, and 22% used other illicit substances.[8]

Mental health and substance use challenges have been shown to negatively impact HIV medication adherence and clinical outcomes across the continuum of HIV care for YLWH.[9 10] For example, in one systematic review and meta-analysis, those with depression symptoms had 42% lower likelihood of achieving 80% or higher ART adherence compared with those without depression.[11] Another found that of those not taking ART, the odds of reporting clinically significant symptoms were three times as high as those on ART, showing the strong relationship between mental illness symptoms and ART uptake and adherence.[12] Another review found that depression and anxiety symptoms in YLWH were strongly associated with ART non-adherence.[13] Additionally, the review found that higher alcohol use in the past week and substance use in the past 3 months were also predictive of poor adherence.

There are few evidence-based counselling interventions for YLWH that address behavioural health factors impacting adherence to HIV care.[13] Interventions developed for adults have shown to be effective in improving depressive symptoms as a method of improving ART adherence.[13] However, young adults differ in multiple ways, including their technology use habits, creating an opportunity for the application of technologies to behavioural health interventions.

As 98% of people aged 18–29 years have a mobile telephone and over 85% have a smartphone, telephone-based interventions are potentially accessible for the majority of YLWH.[14] Most traditional counselling interventions are provided in person and a clinical setting; engaging in these counselling sessions may be a barrier for YLWH who experience transportation or financial issues, stigma or shame around accessing treatment or other challenges.[15] In our formative work, YLWH reported that health-focused mobile interventions could overcome concerns about their ability to effectively and openly communicate with their providers.[16] One survey similarly found that 60% of millennials would be interested in video chat interactions with their medical provider instead of attending in-office appointments.[17]

Several HIV care adherence interventions have been developed for individuals living with HIV, though most are for adults of all ages rather than YLWH. Few of the interventions specifically developed for YLWH use telehealth, texting or other mobile technologies as the platform for intervention delivery.[18] Although these methods have been shown to be promising in improving ART adherence and linkage to care in adults living with HIV, they have been minimally studied in YLWH.[19]

The existing literature on telehealth and texting platforms for HIV-related interventions for YLWH show promising results and highlights the need for additional research in this area.[13] One text message medication reminder system for adolescents and YLWH was shown to be feasible, efficacious and satisfactory to participants.[20] However, a study of 15– to 22-year-old YLWH found that neither a one-way or two-way text messaging intervention significantly improved HIV medication adherence.[21] This highlights the need for additional research on the effectiveness of interventions that combine text messaging with other elements, which may improve efficacy.

In this paper, we describe the protocol for a study to examine the feasibility and acceptability of a novel 12-session telehealth counselling series and accompanying text messages to improve engagement in HIV care, mental health and substance use outcomes. The Youth to Telehealth and Text to Improve Engagement in Care (Y2TEC) intervention is novel in its combination of telehealth and text messaging and strategic integration of three foci (ie, engagement in HIV care, mental health and substance use). We will identify whether these methods are feasible and acceptable to YLWH and will examine preliminary clinical and behavioural outcomes of the intervention. We anticipate that Y2TEC will be feasible and acceptable for counselling YLWH and that participants will show preliminary evidence of improvement in clinical and behavioural outcomes.

METHODS/DESIGN

Study overview and design

The Y2TEC study is a single-site randomised pilot study with the primary aim of examining the feasibility and acceptability of a 12-session telehealth and text message–based counselling series for YLWH. The secondary aim is to evaluate the preliminary impact of the intervention on improved engagement in HIV care, enhanced mental health and reduced substance use for YLWH. The University of California, San Francisco (UCSF) Institutional Review Board (IRB) has reviewed and approved this study. The intervention was designed based on the results of our formative mixed-methods and qualitative research on youth-friendly HIV counselling methods. The intervention is delivered to participants in two condition groups (ie, intervention and waitlist control) via remote telehealth sessions delivered over 4 months, with a crossover design (see table 1). The overall duration of participation is 8 months.

Table 1 Study overview

I=intervention arm participants W=waitlist arm participants X=all participants	Months								
	0	1	2	3	4	5	6	7	8
Screening/enrolment									
Telephone screening	X								
Informed consent		X							
Assessment surveys									
Baseline survey		X							
Follow-up surveys					X				X
Satisfaction and acceptability questionnaire					I				W
Counselling sessions									
Weekly counselling sessions (12)		I	I	I	I	W	W	W	W
Bidirectional text messages									
Monthly check-ins			W	W	W		I	I	I
Session ratings		I	I	I	I	W	W	W	W
Goal reminders		I	I	I	I	W	W	W	W
Session reminders (24 hours and 15 min before telehealth session)		I	I	I	I	W	W	W	W
Community events and resources		X	X	X	X	X	X	X	X
Exit interviews									
Satisfaction survey					I				W
Qualitative exit interviews					I				W

Study setting

Participants are recruited from the San Francisco Bay Area. Participants consent to the study and complete their initial baseline survey in person in a private office at a community-based location or at UCSF's Center for AIDS Prevention Studies. All other study communications are remote via the video chat platform, text messages and telephone calls.

Study participants

The study sample will consist of 80 individuals aged 18–29 years living with HIV, who live in and receive medical care in the greater San Francisco Bay Area. We have chosen to include young adults in this age range as they are in a distinct developmental phase with unique needs and challenges compared with minors or those aged older than 29 years. Other inclusion criteria include English-speaking, willing and able to provide informed consent and have access to a mobile telephone with text messaging capability. Those planning on moving out of California in the next 8 months or with evidence of severe cognitive impairment or active psychosis that may impede their ability to provide informed consent are excluded.

Sample size justification

NCSS and PASS will be used to compute the minimum detectable effect (MDE) sizes, assuming alpha=0.05, power=0.80 and n=64, reflecting anticipated attrition of 20%.[22] For estimates of means and proportions for feasibility and acceptability measures, the minimum detectable distance from the estimate of the proportion to the upper or lower confidence limit is 12.7%, assuming a target of 70% feasibility and acceptability. For means, the standardised distance to the limit is 0.25. For primary preliminary outcome analyses proposed to compare means of continuous outcomes across the intervention and control groups at 4 months, the minimum detectable standardised mean difference d is 0.30. These MDEs are between cutoffs for small (d=0.20) and medium (d=0.50) standardised mean differences suggesting our study is powered to detect small to medium effects.[23]

Patient and public involvement

Prior to the design of this study, we conducted formative research with healthcare providers and patients (Saberi et al, under review), which helped us refine our research questions, study design and outcome measures. We asked YLWH about optimal methods for intervention delivery and considered the requests of several participants to have an initial session face-to-face with the counsellor. Additionally, we involve participants in study recruitment by encouraging active participants to refer others and providing a $25 incentive to both the referee and referred. We will assess the effects and burden of the intervention by the participants themselves through our quantitative survey and qualitative exist interviews after the intervention. We will work with our Youth Advisory Panel and Community Action Board to disseminate the study's results to participants and the community.

General study procedures

Recruitment methods

Participants are recruited through in-person outreach at clinical and community sites serving YLWH, emails to clinics and providers, flyers posted at health clinics and community-based organisations, targeted online advertisements on Instagram, Craigslist, Facebook and Grindr and recontacting participants from prior studies who had expressed interest in being contacted about future studies. Finally, a participant referral method is used, and a $25 incentive is provided to both the referring participant and new participant.

Eligibility screening

Study staff provide a brief overview of the study to prospective participants, answer any questions and complete an eligibility screening on the telephone. Those who meet the inclusion criteria and are willing to participate in the study are asked for a photo ID to verify their date of birth and proof of HIV status (a letter of diagnosis, laboratory results or HIV medication prescription) via a photo text-messaged to the study telephone or by bringing these documents to the initial in-person visit.

Consent and enrolment procedure

The enrolment visit will be completed in person with a study staff member. Participants review the electronic consent form (see online supplementary appendix A) with a study staff member in a private setting. Individuals who are eligible and agree to participate electronically sign the consent and a medical release form using Qualtrics (Provo, UT, USA; version March 2017) an online survey platform and are provided a copy of the Experimental Subject's Bill of Rights.

Baseline survey

Participants then complete the online baseline survey, which takes approximately 30–45 min. Study staff then help participants download a secure video chat mobile application (ie, Zoom, a (Health Insurance Portability and Accountability Act [HIPAA]–compliant video chat platform) on their telephones. Study staff demonstrate how to set up privacy settings on mobile telephones, such as keeping text message previews from showing up on locked screens and adding a security code to lock the telephone.

Randomisation

Following the baseline survey, research staff randomly assign participants to one of two condition groups (ie, intervention or waitlist control) with a prenumbered sealed envelope. Randomisation is done using SAS (version 9.4) based on randomly permuted block sizes to ensure equal-sized groups, and all study staff are blinded to the randomisation order. Approximately 40 participants will be randomised to the immediate intervention condition and receive their first session in person; about 40 participants will be randomised to the waitlist control condition for 4 months after study enrolment and then cross-over to the treatment arm and receive the study intervention entirely remotely with no in-person session with the counsellor. The counsellor and clinical research coordinator will not be blinded to the randomisation condition, as treatment will be prescribed as a result of the condition.

Participant retention

A number of steps are taken to retain participants throughout the study period. Participants are asked for multiple forms of contact information (including emergency contacts, clinical contacts and social media contacts) at the initial visit to prevent loss of contact. They receive three monthly follow-up text messages during the waiting period to confirm their contact information, appointment reminder text messages 24 hours and 15 min before scheduled counselling sessions, birthday text messages and a weekly text message with free fun local activities to facilitate rapport-building (see table 2).

Participants' Incentives

Participants receive up to $310 for completing all study activities, including payments for each counselling session that gradually increase throughout the study (in $10–$25 increments). Participants are given a ClinCard, a reloadable debit card and instructions for use at the initial visit. Participants are also entered into two raffles for chances to win $25 Amazon gift cards when they confirm their contact information or answer two session rating questions after each telehealth session. Additionally, participants who refer others to the study are paid $25 per successful recruitment.

Risks to participants

All risks to participants are monitored by study staff and documented at each session and study assessment. Study staff are trained to thoroughly explain these risks to participants as well as the steps taken to ensure privacy and confidentiality of all information. Safety-related risks to participants could include discomfort due to the sensitive nature of questions in study surveys including substance use, HIV health-related issues and mental health. Non-clinical study staff conducting interviews and participant communication refer to clinical study staff if participant distress is identified. Clinical staff delivering the intervention are trained to assess distress level of participants and refer to established protocols for any participant crisis. If a participant requires treatment due to distress, this will be determined by clinical staff; they will be referred to appropriate services following the crisis protocol, and the principal investigator (PI) will be informed.

Table 2 Text messages

Message	Schedule	Text and response
24 hours Reminder* (A)	24 hours before appointment	If Y: 'Thank you for confirming, Please text us with any questions'. If N: 'Thank you for replying, we will contact you to reschedule'.
15 min Reminder (A)	15 min before appointment	'UCSF Team: Appointment Reminder: See you in 15 min, here is the link (zoom link)'.
Resource (M)	As needed	'UCSF Team: Resources: Here are the resources you requested (link to resources)'.
Goals* (M)	Three business days after session	'UCSF Team: Goals: Were you able to attempt your goal? Yes Or Not Yet'. Response: 'Got it!'
Free Stuff (A)	Weekly	'UCSF Team: Fun Free Stuff: Enjoy Free Yoga in the Park this Saturday from 10 to 11 am, Downtown Oakland. Here's the link (website)'.
Monthly Check-in* (A)	Monthly during waiting period	'UCSF Study Team: Update or confirm your contact info for a chance to win one of 5 $25 Amazon e- Gift cards at the end of the study. Has your phone number or email address changed? Please reply 1 Yes 0 No' If yes: 'Please send us your updated phone number and email address.________ Thank you! You have been entered in the raffle, good luck!' If No: Thank you! You have been entered in the raffle, good luck!'
Survey Link (M)	Baseline, 4 and 8 months	'UCSF Team: It's time for your survey. Click on the link below to complete the feedback survey and receive $10. Thank you! (Survey Link)'
Session Rating* (A)	After each session	'UCSF Team: Please tell us about the session today for a chance to win one of five $25 Amazon e-Gift cards at the end of the study: 1- I felt heard, understood, and respected by the counselor: a. Strongly agree b. Agree c. Neither agree nor disagree d. Disagree e. Strongly disagree 2- Overall, today's session was right for me: a. Strongly agree b. Agree c. Neither agree nor disagree d. Disagree e. Strongly disagree' Response: 'Thanks for your responses! Please let us know if you have any additional comments by texting us'.
Session Completion (M)	After completion of all sessions	'Congratulations on completing the 1st half of the Y2TEC study! Next, you will receive a survey on xx/xx/xx & a final survey on yy/yy/yy. Please let us know if you have any questions. Thanks!'
Waiting Period Completion (M)	After completing waiting period	'Congratulations, you have finished the 1st half of the Y2TEC study! Next, you will receive a survey on xx/xx/xx & we will contact you to schedule your 1st video chat session after you complete your survey. Please let us know if you have any questions. Thanks!'
Birthday Message (M)	On participant's birthday	'UCSF Team: Happy Birthday, we are sending you all our best wishes for a very happy birthday today, cheers!'
Away Message (A)	After hours and holidays	'Thank you for your message! The Y2TEC Study staff are out of the office until XX/XX/XX and will respond after this date. If this is an emergency, please call 911.'
Study Referral (M)	As needed	'UCSF Team: Participants can receive up to $310 for completing all study activities plus $25 per person they refer who enrolls in the study!'

*Bidirectional.
(A)=Automated message.
(M)=Manually sent message.

Adverse events and auditing

The study staff monitor postsession participant ratings (via text message) as one method for identifying those who may have experienced an adverse event. If a participant reports low satisfaction with the intervention, study staff contact them in a timely manner to determine what occurred in the session. Study staff also provide participants with the study mobile telephone number to spontaneously report any adverse events or unintended effects of the intervention. Any adverse events will be documented on an adverse event form, and follow-up will be tracked. The form along with any session notes with details will be reported to the IRB by the PI within 10 working days. The team of investigators will also meet weekly to audit and discuss general trial conduct–related issues.

Protocol amendments

Protocol amendments will be shared with all stakeholders as they occur. Study staff communicate protocol modifications to investigators during monthly meetings, submit changes to www.clinicaltrials.gov as needed, submit IRB modifications and communicate changes to regulators during meetings every 6 months or via email as needed.

Intervention procedure

The 12-session telehealth series is delivered by a trained behavioural health professional (such a social worker, psychologist or psychotherapist), referred to as the 'counsellor' within the context of this study. Sessions use problem-solving, information-motivation-behavioural skills and motivational interviewing and focus on engagement in HIV care, mental health and substance use.[24–26] Telehealth sessions are completed via a secure video chat platform, Zoom, and text messages are sent via a secure encrypted, HIPAA-compliant platform called Mosio.

Series overview

Participants in the intervention arm meet with the counsellor in person immediately after enrolment, and the waitlist control arm participants meet with the counsellor via video chat after 4 months. Before the first meeting, the counsellor reviews the participant's most recent assessment survey responses to determine the participant's level of acuity and tailor appropriate session dosage. Mental health acuity is determined through the Patient Health Questionnaire (PHQ) 9 and PTSD Checklist (PCL); substance use acuity is determined through the Alcohol Use Disorders Identification Test (AUDIT) and Alcohol, Smoking and Substance Involvement Screening Test (ASSIST); HIV care acuity is calculated by a measure of HIV knowledge as well as current participant utilisation of HIV care services and antiretroviral medications. During the first session, the counsellor assesses the participant's needs and identifies current gaps in knowledge and motivation regarding mental health, substance use and HIV care. The first three to six of the remaining 11 sessions cover core psychoeducational and health literacy–promoting content around engagement in HIV care, mental health and substance use challenges and treatments. Those with higher acuity receive two foundational psychoeducational modules rather than one in each of the three areas, amounting to a maximum of six core educational sessions.

The remaining sessions use an integrated behavioural health and HIV care– focused approach to further the conversations initiated in the core sessions. At the beginning of these sessions, the participant and counsellor choose from a list of topics identified in the first session, including HIV care, mental health, substance use, lifestyle health, social support, family of origin, romantic and sexual relationships, self-identity and disclosure, subsistence needs (housing, money and resources) and education and vocation. These sessions can be done in any order and repeated as needed. If a participant is in crisis and unable to be redirected to these options, a 'wildcard' session focused on crisis response and safety planning may be held. The final session includes reviewing the content covered and goals achieved in the previous sessions, identifying unmet needs, accessing community-based resources and learning strategies for maintaining changes.

Scheduling sessions

Four months are allocated to complete the 12 weekly counselling sessions to allow for missed and rescheduled sessions. Participants are encouraged to contact the counsellor or study staff to reschedule their appointments as needed. Participants receive session reminders via text message 24 hours and 15 min before each session.

Session documentation and fidelity

The counsellor completes session summary notes through a Qualtrics survey form, which includes closed-ended and multiple-choice questions such as session length, participant location, technical issues encountered, session topics selected, educational topics covered, goals set, a session content fidelity checklist and a narrative progress note.

Evaluation and curriculum modifications

The initial version of the Y2TEC intervention will be delivered to participants randomised to the intervention arm. The research team plans to adjust the intervention based on lessons learnt and feedback from participants to develop a modified version of the intervention (ie, intervention manual version 2.0). This version will be provided to all waitlist control participants, and outcome differences between the two arms will be explored during analysis. As a result, the intervention will have gone through an iterative refinement process and will be ready for implementation in a larger randomised controlled trial by the end of the pilot study.

Data collection and management procedure

Clinical data collection

At consent, participants sign a medical release form, and research staff obtain medical records from participants' respective medical clinics at baseline, 4 months and 8 months. Information collected includes appointment

Table 3 Measures in participant surveys

Domain (in order of the survey)	Measure	Baseline survey	Follow-up surveys
Demographics	Original measure	X	
Use of technology	Original measure	X	
HIV treatment outcomes, antiretroviral history and adherence	Original measure	X	X
HIV knowledge	HIV Treatment Knowledge Scale[34]	X	X
Alcohol use	Alcohol Use Disorders Identification Test[35]	X	X
Substance use	Alcohol, Smoking and Substance Involvement Screening Test [36] Q2 , Drug Abuse Screening Test-10[37]	X	X
Depression	Patient Health Questionnaire-9[38]	X	X
Adverse childhood experiences	Adverse Childhood Experience Questionnaire[39]	X	
Trauma/PTSD	PTSD Check List[40]	X	X
Anxiety	Generalised Anxiety Disorder-7[41]	X	X
Sleep	Pittsburgh Sleep Quality Index)[42]	X	X
Resilience	Connor-Davidson Resilience Scale[43]	X	X
Internalised HIV stigma	HIV Stigma Mechanisms[44]	X	X
Mental health and substance use stigma	SAMHSA Mental Health and Alcohol Abuse Stigma Assessment[45]	X	X
Social support	Medical Outcomes Study Social Support Scale[46]	X	X
Social isolation	Patient-Reported Outcomes Measurement Information System[47]		X
Healthcare empowerment	Healthcare Empowerment[48]	X	X
Relationship with healthcare provider	Healthcare Provider[49]	X	X
Unmet subsistence needs and instrumental support	Medical Outcomes Study Short Form[50]	X	X
Satisfaction and acceptability	Original measure		X

PTSD, posttraumatic stress disorder; SAMHSA, Substance Abuse and Mental Health Services Administration.

attendance, medications and laboratory data including plasma HIV RNA and CD4+ cell count. The data point closest to baseline, 4 months and 8 months ± 1 month are used for data analysis.

Assessment data collection

Participants complete assessment surveys at baseline, 4 months and 8 months after enrolment. The surveys collect demographic, technology use, substance use, mental health and HIV care information (see table 3). The baseline surveys are completed online in-person at the initial visit, and the other two are completed remotely on the participants' mobile devices.

Qualitative data collection

A subset of approximately 20 participants who have finished the intervention will be invited to complete an audio-recorded telephone semistructured individual qualitative exit interview with study staff for a $30 payment. Participants will be chosen to reflect a range of levels of engagement and attendance using a question adapted from the Session Rating Scale[27] to determine the level of satisfaction with each telehealth session. Using mean scores of participant satisfaction over 12 telehealth sessions and attendance, participants will be divided into four groups: (1) high attendance, high satisfaction; (2) high attendance, low satisfaction; (3) low attendance, high satisfaction; and (4) low attendance, low satisfaction. Five participants will be randomly selected from each category and interviewed. Participants will receive information and consent for the qualitative interviews during the initial visit, along with the consent for the rest of the study. The interviews will focus on the acceptability of the intervention and participant feedback on the intervention, and the interviews will be audio- recorded and transcribed verbatim.

Table 4 Primary outcome measures: feasibility and acceptability

Primary outcome measures	Metrics	Acceptance criteria
Acceptability	Measure participant satisfaction with the telehealth intervention at completion of intervention by a 30-item questionnaire (1 excellent to 6 unsatisfied) administered through an online survey	Mean satisfaction score≥80%
	Measure participant satisfaction with each telehealth session via 2-item scale (1 strongly agree to 4 strongly disagree) administered via text messaging	Mean satisfaction score≥80% over 12 telehealth sessions
Feasibility	Recruitment	At least 70% of the planned 80 participants (ie, n=56)
	Participant retention at 4 months	At least 80% of participants retained in the study at 4 months
	Participant retention at 8 months	At least 60% of participants retained in the study at 8 months
	Number of telehealth disconnections	Mean of one disconnection per videoconferencing session
	Participant response time to texts	Mean of 3 days between bidirectional text message and participants' response
	Sound quality based on a one item questions using Likert scale (0–10) (0=poor quality; 10=excellent quality) as rated by counsellor	Mean of 7 out of 10 sound quality
	Video quality based on a one item question using Likert scale (0–10) (0=poor quality; 10=excellent quality) as rated by counsellor	Mean of 7 out of 10 video quality

Confidentiality and data protection

All screening and consenting will take place in a private room. Study staff will use a secure, encrypted texting platform for all study text communication. Participants will receive support from study staff who will demonstrate how to set up additional privacy measures using the settings on their personal mobile telephones. Electronic data will be gathered through HIPAA-compliant platforms, stored on a secure network and password protected. Subjects will be coded by numbers and with no names; linking information will be kept in locked files. The data will not be shared unless via a data use agreement including deidentified data. The study has obtained a Certificate of Confidentiality from the National Institutes of Health to protect the privacy of potential and enrolled study participants.

Data monitoring

A Data Monitoring Committee (DMC), interim analyses and stopping guidelines are not needed because the study is a pilot feasibility study that has been classified as minimal risk by the UCSF IRB.

Study outcomes

Feasibility, acceptability and clinical outcomes

Preliminary data on feasibility, acceptability and HIV clinical outcomes will be gathered throughout the study (see tables 4 and 5). Acceptability of the telehealth intervention will be determined throughout the study using several methods. Study staff will administer two-session rating questions via text after each weekly telehealth session, asking if the participant 'felt heard, understood and respected by the counsellor' and if the 'session was right' for them. Additionally, a 30-item exit survey is administered through Qualtrics after the intervention is completed, including questions pertaining to (1) the overall rating of the study; (2) satisfaction with each study procedure; (3) ease or difficulty with each study procedures; (4) helpfulness of communication with study staff; (5) self-perception of improved ART adherence, mental health and substance use with study participation; (6) recommending a study similar to this to a friend; and (7) participating again in a similar study. Study staff will also conduct qualitative exit interviews with 20 participants to gather in-depth descriptions of participant experiences, perceptions and acceptability of the intervention. Clinical outcomes within the two study arms include HIV RNA, CD4+ cell count, self-reported adherence, appointment attendance, substance use (Drug Abuse Screening Test [DAST] and ASSIST) and mental health (PHQ-9 and PCL-5; see table 5).

Data analysis plan

Quantitative analysis plan

One-way frequency tables will be generated for all baseline and follow-up survey questions, and measures of central tendency and variability will be computed for continuous measures. Results from these analyses will

Table 5 Secondary outcome measures: clinical impact

Secondary outcome measures	Metrics
Alcohol use	Measure participants' alcohol use from baseline to 4 and 8 months using the Alcohol Use Disorder Test (AUDIT), a 10-item questionnaire to measure severity of participants' alcohol use. Responses are summed. Scoring range is 0–20+; 0–7: Low alcohol use, 8–19: Moderate alcohol use, 20+: High alcohol use/dependence.
Depression	Measure participants' depression from baseline to 4 and 8 months using the Patient Health Questionnaire 9, a 9-item Likert scale score (0–3) 0 'not at all', 3 'nearly every day'. Responses are summed. Scores will have a range of 0–27. PHQ-9 scores of>10 are associated with moderate to severe depression.
Frequency of Substance Use	Measure participants' change in substance use from baseline to 4 and 8 months using a 10-item questionnaire (ASSIST) to measure frequency of participants' substance use.
Posttraumatic stress disorder (PTSD)	Measure participants' self-reported PTSD from baseline to 4 and 8 months using the PTSD Checklist—revised, a 20-item Likert questionnaire administered through an online survey. Scoring: 0 points for 'not at all', 1 point for 'a little bit', 2 points for 'moderately', 3 points for 'quite a bit', 4 points for 'extremely'. Scores will have a range of 0–80. Responses are summed.
Self-reported medication adherence	Measure changes in participants' self-reported medication adherence based on 1-item adherence rating (1 excellent to 6 poor, lower rating indicates higher adherence) from baseline to 4 and 8 months.
Severity of substance use	Measure participants' changes in substance use from baseline to 4 and 8 months using the Drug Abuse Screening Test, a 10-item questionnaire to measure severity of participants' substance use. Responses are summed. Scoring (0–10); 0–2 low substance use, 9–10 severe substance use.
Measure of participant HIV knowledge using HIV Treatment Knowledge Scale	Assess participants' knowledge of HIV from baseline to 4 and 8 months through the HIV Treatment Knowledge measure, a 15-item self-report questionnaire. Scoring out of 15 (0–12 inadequate, and 13–15 adequate). Scores will have a range of 0–15.

ASSIST, Alcohol, Smoking and Substance Involvement Screening Test .

quantify important sample characteristics and participant use of various telehealth modalities as well as proportions and means of the feasibility and acceptability measures. Primary preliminary outcome analyses will use linear mixed models to compare mean log10 HIV RNA across the intervention and control groups at 4 months relative to baseline. Secondary exploratory preliminary outcome analyses will use the same analytic methods to compare the 8-month time point within the intervention arm to baseline to examine whether the intervention had longer-term effects. A parallel exploratory analysis will compare waitlist controls at 4 months versus 8 months.

Additional secondary exploratory analyses will repeat this set of analyses on other secondary outcomes such as CD4+ cell count, HIV knowledge, self-reported adherence and appointment attendance, PHQ-9 and PCL-5 mental health measures, AUDIT alcohol use measure and the DAST substance use measure. Finally, all analyses described above will be repeatedly stratified by participant gender to explore whether there is any evidence of gender differences in effects. Due to the modest sample size and pilot focus of the study, significance testing will be de-emphasised in favour of performing inferential analyses as a feasibility check to ensure all measures and analysis protocols are in place for a larger formal efficacy trial.[28 29]

Qualitative analysis plan

Study staff will complete, audio- record and transcribe individual in-depth interviews with 20 YLWH following completion of the clinical intervention. The analytic team will identify broad themes from the interview transcripts, discuss and refine them and then enter them into a Microsoft Excel–based matrix with a column for each theme and a row for each case. One coder will initially identify patterns in the themes and code each interview to identify subthemes, and a second coder will double code a random subsample (n=5) of the interview codes within the matrix. Discrepancies in coding will be discussed by the team until a consensus is reached and interrater reliability will be calculated. A sequential mixed-method design will be used to integrate our quantitative and qualitative data analysis.

Dissemination plan

Study staff will work with the UCSF Centre for AIDS Prevention Studies' Community Engagement Core and the Youth Advisory Board to disseminate results to the community and participants via presentations, community forums, email updates and/or social media. Study staff will conduct town hall presentations and publish findings in peer-reviewed journals to communicate results with healthcare professionals.

DISCUSSION

This study protocol describes the Y2TEC pilot, randomised, cross-over study designed to impact the mental health, substance use and HIV care challenges of YLWH. Few interventions for YLWH currently exist that address these three concerns in an integrated way, and as a result, we had few examples of similar curricula while developing the Y2TEC intervention. Therefore, we relied on formative research including qualitative interviews with healthcare providers and staff serving YLWH, as well as a mixed-methods study examining HIV care engagement, mental health, substance use and technology-based interventions to address these issues with the target population [Saberi *et al*, under review,[15]].

Additionally, in our review of existing telehealth interventions focusing on these areas, we discovered that there were general telehealth guidelines but few specifics for research. For example, telehealth-specific regulations on best practices for responding to mental health crises described general practices for clinicians with little mention of best clinical practices for crisis response within a research setting.[30 31] We also found that there were few sources of information about best practices for using text messaging and telehealth counselling within research settings, as many healthcare providers who are currently holding telehealth appointments are practicing within medical groups that have officially adopted these technologies.[32]

This study has several unique aspects that are worth highlighting. This intervention explores non-traditional methods for care provision that deviate from the adult-care models and may be considered more 'youth friendly'.[33] The intervention was specifically designed to be tailored and adaptable to the participant using the results of the participant's assessment responses to inform the counsellor's decision-making around the number of educational and problem-solving sessions on particular topics. As a result, the counsellor is given the ability to spend more or less time on HIV care, mental health or substance use based on the acuity of the participant's need. Though this adaptive modular structure adds complexity, it has the potential to better meet the needs of participants than a more rigidly structured intervention.

Furthermore, this study simultaneously explores several unique aspects of feasibility and acceptability. In addition to exploring whether this form of intervention will impact HIV, mental health and substance use outcomes, we are also considering the acceptability of a fully online versus hybrid in-person online session delivery. Half of the participants receive the first intervention session with the counsellor in person and the rest of their sessions remotely, and the other half receive the full series remotely. If shown to be similarly acceptable, this intervention can be offered completely remotely.

The Y2TEC counselling series has been designed with replication and scalability in mind. The intervention is unique in the relatively low clinician time burden (6 hours of individual counselling per participant over 4 months) compared with traditional face-to-face counselling, which often involves weekly hour-long sessions (which may total 12–16 hours over 4 months). Additionally, if we find that participants perceive the remote-only counselling option as acceptable, implementing the intervention would require minimal office space and physical materials, limiting factors within healthcare settings. A remote-only counselling intervention would also potentially increase access for those living in rural areas with limited access to transportation or local services.

We anticipate that the findings of our study will show that a telehealth and text message–based counselling series for YLWH will be acceptable and feasible. We expect that the findings from this study will provide information about additional ways of using new mobile technologies to support the HIV care goals and behavioural health needs of YLWH and will help influence the development of additional mobile-based counselling strategies. The results of this pilot study will allow us to conduct a larger multicentre randomised controlled trial to examine the efficacy of this intervention.

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Contributors PS, CDR and MOJ conceived the study and developed the experimental design and measures. ARW and VAG developed the telehealth counselling intervention and manual. DAL and PS developed the main study protocols. ARW and DAL carried out the daily study activities. TBN contributed to the data collection and analysis plan. All authors were involved in the revision of the draft manuscript and have agreed to the final content.

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EDITORIAL REVIEW

Mental health and HIV/AIDS: the need for an integrated response

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Tremendous biomedical advancements in HIV prevention and treatment have led to aspirational efforts to end the HIV epidemic. However, this goal will not be achieved without addressing the significant mental health and substance use problems among people living with HIV (PLWH) and people vulnerable to acquiring HIV. These problems exacerbate the many social and economic barriers to accessing adequate and sustained healthcare, and are among the most challenging barriers to achieving the end of the HIV epidemic. Rates of mental health problems are higher among both people vulnerable to acquiring HIV and PLWH, compared with the general population. Mental health impairments increase risk for HIV acquisition and for negative health outcomes among PLWH at each step in the HIV care continuum. We have the necessary screening tools and efficacious treatments to treat mental health problems among people living with and at risk for HIV. However, we need to prioritize mental health treatment with appropriate resources to address the current mental health screening and treatment gaps. Integration of mental health screening and care into all HIV testing and treatment settings would not only strengthen HIV prevention and care outcomes, but it would additionally improve global access to mental healthcare.

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Introduction

Tremendous advances have been made in HIV prevention and treatment since the discovery of the virus that causes AIDS. Today, most people newly diagnosed with HIV can expect a near normal lifespan with steady access and adherence to combination antiretroviral therapy (cART). Moreover, in recent years there is great optimism about the potential to end the HIV epidemic – or at least substantially 'bend the curve' of the epidemic – with current biological and behavioral tools. Preexposure prophylaxis (PrEP) is highly effective at protecting individuals from acquiring HIV when taken consistently [1]. Further, people living with HIV (PLWH) who maintain durable viral suppression do not transmit the virus to sexual partners, and in the case of pregnant women, to infants via pregnancy and delivery [2–4].

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Given these advances, many jurisdictions are making concerted efforts to turn the tide of the epidemic through PrEP scale-up for individuals vulnerable to acquiring HIV, and improved HIV diagnoses and rapid provision of cART for PLWH. The Joint United Nations Programme on HIV/AIDS (UNAIDS) goals of '90–90–90' call for 90% of PLWH to be diagnosed, with 90% of them initiating cART, and 90% of people initiating cART to achieve and sustain viral suppression through adherence to the treatment [5]. Some localities are moving toward even more ambitious goals of '95–95–95' and ultimately 'getting to zero' new HIV infections [6]. Although these goals are aspirational, many believe they are achievable with focused resources and concerted efforts.

However, these gains will not be achieved without addressing the significant mental and substance use problems among people vulnerable to acquiring or living with HIV, which exacerbate the many social and economic barriers to accessing adequate and sustained healthcare [7–12], and are among the most significant barriers to achieving the 90–90–90 targets [7–12]. We posit that it will be impossible to significantly 'bend the curve' and approximate an ending of the HIV epidemic without dramatically altering our approach to diagnosing and addressing comorbid mental health (including substance-use) problems among people most vulnerable to HIV.

Global burden of mental and substance use problems

In the general population, mental and substance use disorders are the number one contributors to number of years lived with disability, with greater impact than other communicable, maternal, neonatal, nutritional, and noncommunicable diseases, including HIV, and injuries [13]. Excess mortality among persons with mental, neurological, and substance use disorders is evident, with a shortened life span of approximately 15–20 years. The global burden of these disorders rises in late adolescence and peaks in young adulthood, which emulates the global HIV burden.

Mental health and HIV acquisition

Mental health disorders play a critical role in HIV acquisition across populations, increasing the risk of HIV acquisition by 4–10-fold [14,15]. In the United States, the prevalence of HIV is substantially higher among adults with serious mental illness (SMI; e.g. psychotic disorder, bipolar disorder, recurrent major depressive disorder, comorbid mood, and substance use disorder) – ranging from 2 to 6% – compared with the general population (0.5%) [16–18]. In Africa, where the HIV burden is even greater, the prevalence of HIV among adults with SMI ranges from 11 to 27% [19–22].

Mental health problems can increase risk of HIV acquisition through both direct and indirect pathways. Although people with SMI tend to be less sexually active compared with the general population, sexually active adolescents and adults with SMI evidence higher risk sexual behavior, including inconsistent condom use, having multiple sexual partners, trading sex, and drinking alcohol before sex [23–29]. The risk of HIV infection may also increase with severity of psychiatric illness. In a multisite study in the United States, the prevalence of HIV among persons with SMI rose from 3.9% in community mental health centers, to 5.1% in intensive outpatient case management programs, to 5.9% in psychiatric inpatient units [16]. HIV risk may be further compounded when there are multiple co-occurring conditions, such as a mood disorder, substance use disorder, and posttraumatic stress symptomatology from (for example) physical, sexual, or emotional abuse. A large multisite study of US MSM found a significant positive dose-response relationship between the number of co-occurring conditions and risk of HIV acquisition: men with four to five co-occurring conditions had more than eight times the hazard of HIV infection compared with those with no such conditions [30]. Mental health problems can also interfere with efforts to prevent HIV infection, including regular HIV testing and adherence to PrEP [31–33]. In the iPrEx and iPrEx-OLE trials, which studied PrEP efficacy and open-label use among MSM and transgender women, participants with higher depression scores had lower levels detectable PrEP medication (emtricitabine and tenofovir disoproxil fumarate) and higher levels of condomless receptive anal intercourse [34,35]. Screening and treatment for mental health problems and disorders will be essential to preventing vulnerable populations from acquiring HIV.

Prevalence of mental health disorders among people living with HIV

Many studies have shown that PLWH experience higher rates of mental health disorders than the general population. This includes research conducted with diverse groups of PLWH such as youth with perinatal or behaviorally acquired HIV, adult MSM of color, racial and ethnic minority women, people who inject drugs (PWID), and older adults [36–42]. In a US multisite study with over 2800 PLWH, 36% had major depression and 15.8% had generalized anxiety disorder [36], compared with only 6.7 and 2.1%, respectively, in the general population [43]. Other studies from North America have shown similarly higher rates of mental health disorders among PLWH. PLWH presenting at an academic medical center in the Southeastern US showed high levels of mood disorder in the past year (32%) and past month (21%), as well as anxiety disorder in the past year (21%) and the past month (17%) [44]. In Ontario, Canada, available electronic medical records indicated that 41% of PLWH had a mental health condition compared with 22% among non-HIV infected adults [38]. A study by Blank *et al.*, conducted HIV tests with over 1000 people who were seeking mental healthcare at university-based psychiatric inpatient units, intensive case-management programs, and community mental health centers. They found that 4.8% had confirmed positive HIV tests – much higher than the HIV prevalence rate in the general US population [16]. Data from across the globe also indicates elevated rates of mental health disorders among PLWH compared with the general population. For example, a study among PLWH in India showed that 59% had signs of major depression [45]. In China, a recent review found prevalence of depressive symptoms in 61% of PLWH [46]. In Uganda, major depression was found in 14% of 1099 cART-naïve PLWH [47]. In South Africa, 26–38% of PLWH are estimated to have a mental disorder compared with 13% in the general population [48]. Although major depression is one of the most commonly seen mental health disorders in PLWH, rates of posttraumatic stress disorder (PTSD) are also much higher among PLWH than in the general population, ranging from 10 to 74% [49–52] compared with only 8% in the US general population [49–53]. Prevalence of substance use disorders also tend to be higher among PLWH than in the general population ranging from 21 to 71% [44,54], as do rates of neurocognitive impairment – about 50% of PLWH, even those who are virally suppressed [55].

Intersecting vulnerabilities

Many factors contribute to the high comorbidity of HIV and mental health conditions. People who have (or are at risk for) HIV and who are vulnerable to mental health conditions often face other significant individual, structural, social, and biological challenges to accessing and adhering to HIV prevention and treatment modalities. These factors fall into the domains of sociodemographics, neighborhood and local environmental factors, social structures, individual biology, and intersecting societal stigmas. Structural factors, including poverty, low education, unstable housing, and food insecurity, contribute to increased vulnerability to HIV infection and poor HIV health outcomes [56,57]. Neighborhood and environmental factors, including violence and lack of safety, lack of adequate safe and steady water supply, wars, and natural disasters, cause psychological trauma, disrupt the delivery of medical supplies, and present barriers to healthcare access [58–60]. Biological factors, including comorbid communicable diseases (e.g. tuberculosis, hepatitis) and noncommunicable diseases (e.g. diabetes, heart, and bone disease), as well as chronic immune activation, contribute to poorer physical and mental health outcomes [61,62]. Intersecting social stigmas, and criminalization in some contexts (e.g. sex work, drug use, and same-gender sex) present additional challenges to key populations that are highly affected by HIV, including MSM, transgender women, sex-workers, people who use drugs (including PWID), and racial and ethnic minorities. These groups experience perceived and internalized stigma as well as enacted stigma (e.g. discrimination) that negatively affect mental health, and this relationship is further compounded by the unfortunate stigma of mental illness in society and among patients and providers [63–65].

Mental health impairment and outcomes along the HIV care cascade

There is substantial evidence that impairment in mental health leads to negative health outcomes at each step in the HIV care continuum, starting with being diagnosed with HIV, all the way to achieving viral suppression. Lack of HIV diagnosis jeopardizes the health of PLWH by impeding access to the significant health benefits that cART confers. Lack of HIV diagnosis presents a further public health challenge because a substantive proportion of new HIV infections are attributable to persons who are not aware of their HIV status [66–72]. Mental health impairment that results from having a mental health disorder (e.g. major depression, alcohol or other substance use abuse or dependence) or significant levels of psychiatric distress (e.g. elevated depressive, anxiety, or PTSD symptoms) can interfere with regular HIV testing and learning one's HIV status, as well as successfully linking to HIV healthcare, staying in care, initiating cART, and remaining adherent to cART to achieve HIV viral suppression [66–72].

Mental disorders can present a substantial barrier to adequate engagement and retention in HIV primary care. Research has established links between the presence of psychiatric illness and poor rates of HIV care linkage and retention. In one Alabama study, missed HIV primary care visits during the first year of care were more common among patients who had substance abuse disorders, as well as those who were younger, female, black, and lacking private health insurance [73]. A large cohort study of PWIDs found that only 30.5% were continuously retained in HIV care over nearly 9 years of follow-up, and that active drug use was associated with lower care retention [74]. The preponderance of research therefore indicates that substance use disorders represent a frequent impediment to timely HIV care linkage as well as sustained retention in care [75].

The aspect of the HIV care continuum which has been most studied in relationship to mental health is cART adherence. Research has clearly identified depression as one of the strongest predictors of poor cART medication adherence [68]. A large meta-analysis found a significant association between depression and cART nonadherence across 95 independent samples [68], and determined that the likelihood of achieving good (80%) cART adherence was 42% lower among those with depressive symptoms than those without depressive symptoms across 111 independent samples. This robust finding was consistent across low, middle, and high-income countries [72]. Another large review and meta-analysis that synthesized 125 studies with a total of 19 016 patients across 38 countries found that self-reported depression and alcohol and other substance misuse were among the top 15 barriers to adherence, along with other reasons such as forgetting, being busy, a change in routine, and the experience of medication side effects [76]. In perinatally infected youth, for whom nonadherence to treatment across health conditions is a significant issue [77], a range of psychiatric disorders, not just mood disorders, have been associated with nonadherence to HIV treatment and elevated viremia [78].

Mental health impairment clearly contributes to poorer healthcare behaviors across the HIV care continuum, leading to negative HIV health outcomes (i.e. elevated viral load, decreased $CD4^+$ levels, and increased opportunistic illnesses). There is also evidence, however, that suggests a direct biological pathway from mental health impairment to poorer HIV health outcomes, especially in the context of depression.

Depression, HIV, and the immune system

There is evidence suggesting a bi-directional relationship between depression and the immune system [79–81]. Depression is known to negatively affect the immune system (e.g. $CD4^+$ cell decline) although the underlying mechanisms remain poorly understood. Chronic immune activation and hypothalamic–pituitary–adrenal axis dysregulation [82,83], which HIV infection can exacerbate [84–86], are established factors contributing to developing depression and likely contribute to high rates of depression among PLWH [62]. HIV crosses the blood brain barrier causing immune activation in the brain and the central nervous system [87]. Inflammatory proteins (e.g. C-reactive protein, cytokines) lead to oxidative stress and neuronal injury [88], specifically, the chronic inflammatory response to HIV infection leads to elevated cytokine levels, including IL-6 and TNF-α, which can trigger a chain reaction involving Tryptophan depletion through the activation of Indoleamine 2,3-dioxygenase enzyme [82,89,90]. Tryptophan depletion leads to reduced serotonin levels and increased Kynurenine and its metabolites, which are neurotoxic and associated with depression, suicide, anxiety, and physical health conditions, such as cancer, cardiovascular diseases and premature death [91–94]. Therefore, it is possible that chronic inflammation and tryptophan depletion contribute to the deleterious effects of depression on physical health outcomes.

Depression and mortality in the HIV context

Depression has been shown to increase the risk of mortality among PLWH [41,95]. For example, among 1487 women followed for 24 months in Tanzania, mortality was 6.6% among women with depressive symptoms versus 3.7% among women without depressive symptoms [66]. And among 765 HIV+ women at four US sites followed for up to 7 years, women with chronic depressive symptoms were twice as likely to die as women with limited or no depressive symptoms, even after adjusting for predictors of mortality (i.e., $CD4^+$ cell count, cART duration, age) [41]. In the Women's Interagency HIV Study prospective cohort ($N = 848$), chronic depressive symptoms were associated with over three times the hazard of mortality, among women on cART, and over seven times the hazard of mortality, among women not on cART, compared with women on cART with no depression [96]. Examining medical records of close to 6000 ($N = 5927$) PLWH, a dose–response relationship was found between depression length and HIV outcomes. For every 25% increase in days experiencing depression, there was a 19% increase in the risk of mortality [95].

Screening and treatment for mental health problems

Given the strong evidence for the contribution of mental health and behavioral problems to poor HIV health outcomes, there is an obvious need for universal mental health screening and the provision of mental health treatment integrated into ongoing HIV care. There is a wide array of mental health screening tools that are being used in clinical care as well as in research, and they have been validated across many regions of the world, including in low-income and middle-income countries [97]. Screening for mental and behavioral problems is insufficient and arguably unethical to conduct, if follow-up treatment is not made available for those who screen positive and are in need. To advance the provision of mental healthcare, there exists a wide-range of effective mental health treatments including psychopharmacological treatment, and various psychotherapies (e.g. psychodynamic, cognitive-behavioral therapy, motivational enhancing therapy, and interpersonal therapy), stress reduction and mindfulness treatments, and harm reduction and abstinence treatments. Many of these approaches have been manualized and tailored across languages and cultures [51,98–101].

The broader challenge is that most people (70–85%) with mental disorders, across all country settings, do not receive the needed mental healthcare, in part because they are not even identified as having a mental health disorder [102–107]. Many factors contribute to this gap in mental health screening and provision of treatment, including human resource shortages, fragmented service delivery models, and lack of capacity for implementation and policy change. A central challenge is the stigma of mental illness that exists at all levels: patients, healthcare workers, and policy makers. According to the WHO, worldwide mental health budgets are significantly underfunded, with expenditure on mental healthcare being approximately one percentage of total expenditure on all of healthcare [108,109]. Further, looking at the availability of mental health professionals for the population, there are significant disparities between low-income and middle-income countries and high-income countries, with inadequacy across all settings. This is particularly true in low-income countries, where there is a dramatic paucity of providers, such as one psychiatrist/psychologist per 1.5 million people in South Africa, and 12 psychiatrists/16 psychologists per 13 million people in Zimbabwe [108,110,111].

Mental and behavioral health treatments for people living with HIV

Large systematic reviews and meta-analyses demonstrate that PLWH can benefit from a broad range of mental and behavioral health interventions [98–100]. Mental health research conducted with PLWH in low-income, middle-income, or high-income countries has tested pharmacological interventions and various psychological and psychosocial interventions (e.g. cognitive behavioral therapy, interpersonal therapy, group therapy, motivational interviewing, stress management, meditation, and psycho-educational family interventions). The duration of the tested interventions varies considerably, ranging from 1 to 30 hours, 1 to 54 weeks, and 1 to 48 sessions. The research syntheses report small to moderate positive effects of these interventions on mental health among PLWH, with demonstrated reductions in depression and anxiety, and improved quality of life and psychological well being. Some of the largest and most consistently positive effects have been seen among interventions delivered by mental healthcare professionals over lengthier intervals, and which primarily focus on mental health. Psychological interventions with cognitive-behavioral components were consistently effective. Psychotropic and HIV-specific health psychology interventions were generally effective, with some mixed findings. Within low-income and middle-income countries, multilevel interventions that were integrated into community-based healthcare and which included family interactions or peer support were among the most effective.

Although the evidence base for mental health interventions among PLWH is encouraging, several limitations are also evident. The preponderance of research on mental health interventions for PLWH has been conducted in high-income countries (and particularly in the United States) rather than low-income and middle-income countries, which is a mismatch to the global burden of HIV [98–100]. This gap could be addressed by drawing upon lessons learned from the large evidence base for delivering mental health interventions with fidelity and effectiveness in general populations using nonskilled personnel (i.e. task-sharing or task-shifting) in low-income and middle-income countries [112]. Mental health intervention trials with PLWH have also generally focused on short-term over long-term outcomes [98,99], and the research could benefit from improved quality and rigor [100]. There is also a paucity of studies that examine mental health interventions in relationship to HIV care outcomes, relative to studies that focus on mental health outcomes alone. Finally, few evidence-based mental health interventions have been tested with youth. One exception is the CHAMP+ program, based on the Collaborative HIV/AIDS Mental health Program [113], a family-based intervention originally developed in the United States to prevent HIV risk behaviors and promote mental health in vulnerable communities of adolescents, and that has been successfully adapted for South Africa [114] as well as Asia [115–117]. However, given the staggering numbers of children and adolescents with HIV globally [118,119], particularly in sub-Saharan Africa, there is a substantive need for development of more evidence-based mental health interventions focused on this particularly challenging developmental stage [40,120].

Scale-up of interventions: challenges and solutions

There are substantial challenges to the provision and scale-up of mental health screening and treatment for those in need, particularly within resource-constrained settings where HIV is endemic and the availability of mental health professionals and services is rare. The following four models offer promising approaches to efficient and effective mental healthcare delivery in resource-constrained settings: task shifting, stepped care, trans-diagnostic approaches, and technology.

Task shifting is a method of strengthening and expanding the health workforce by shifting responsibilities from highly qualified health workers to health workers with less training and fewer qualifications [121]. In the context of mental health screening and treatment, this represents a shift from mental health professionals to healthcare workers who lack formalized training in mental health. There are a few examples of this occurring with some success in HIV care settings. For example, a cluster randomized controlled trial conducted at ten clinics in Uganda studied two task-shifting approaches to integrating depression treatment into HIV care: delivery of depression screening and treatment by trained nurses using a structured protocol, or by trained primary care providers (PCP) using their own 'clinical acumen' rather than a structured protocol [122]. Successful screening occurred in 76% (nurses) and 80% (PCP) of cases, with clinically depressed patients being prescribed antidepressants in 69% (nurses) and 56% (PCP) of cases, and with treated patients achieving full remission of their depression being 65% (nurses) and 69% (PCP). The authors concluded that existing clinic staff (nurses, doctors) can provide quality depression care with limited training and supervision by available mental health specialists.

Stepped care approaches find efficiency by triaging intervention intensity based upon observed need [123]. Patients who do not benefit from initial, lower intensity interventions graduate to higher intensity or more resource-intensive interventions. Stepped care approaches have been used by several HIV-related mental health projects in sub-Saharan Africa. For example, a project in Zimbabwe piloted a stepped-care and task-shifted intervention for HIV patients with depression and low antiretroviral adherence [124]. Lay community health workers were trained to deliver a first-level intervention to patients (six sessions of problem-solving cognitive behavioral therapy for depression and medication adherence). Patients who did not benefit from the first-level intervention were triaged to more intensive treatment (an assessment by a trained clinician for potential provision of antidepressants and/or further counseling). A small pilot trial found reduced depression and improved viral load suppression among intervention recipients compared with enhanced standard care [124].

Transdiagnostic approaches represent another route to advance delivery of HIV-related mental healthcare in resource-constrained settings. Transdiagnostic approaches recognize that different mental disorders (e.g. depression, anxiety) frequently co-occur and may share-related symptomatology, so uniform treatment strategies might be employed to effectively address multiple mental health problems [125]. Applications of transdiagnostic approaches to HIV include cognitive-behavioral counseling to concurrently address depression, anxiety, and HIV risk related to minority stress among young gay and bisexual men in the United States [126]. Outside of HIV, randomized trials found that a transdiagnostic psychotherapy toolkit delivered by lay counselors successfully treated symptomatology from multiple trauma-related disorders among Burmese refugees [127] as well as survivors of violence in Iraq [128].

Finally, technology-based approaches like telephone-delivered and computer-delivered interventions can help scale mental healthcare and support lay-counselor interventions with PLWH who are in need [129,130]. Internet-based mental health interventions, such as internet-based cognitive behavioral therapies [131] are growing in popularity globally to improve access in low resource contexts, as well as among youth and young adults who are at high risk for nonadherence or nonaccess of mental health resources [132].

Community and public health messaging to reduce HIV-related psychological distress

Since the stigma of HIV can lead to significant psychological distress, community and public health campaigns to reduce stigma may have a substantive mental health effect. Improved access to and understanding of HIV treatment and prevention could particularly reduce HIV stigma and benefit mental health. Findings from the HPTN 052 trial and PARTNER studies have definitively demonstrated that HIV treatment is prevention [3,4]. Community advocates have built on this science by advancing a messaging campaign regarding 'U = U' (undetectable = untransmittable), which states that PLWH with sustained HIV viral suppression cannot transmit HIV through sex [133,134]. The campaign holds that the optimistic messaging of U = U will build hope in the community and contribute to a lessening of HIV-related stigma, which in turn can reduce psychological distress among PLWH and their sex partners. Community advocates and anecdotal reports indicate that the U = U message helps many PLWH feel unburdened by the shame and stigma that accompanies HIV infection [133]. There is a need for systematic research on patient understanding of U = U and its potential benefits for mental health and well being among PLWH.

Increased availability and use of effective HIV primary prevention tools could importantly benefit mental health, as well. The high efficacy of PrEP in nearly eliminating the risk of HIV acquisition among HIV-negative individuals adhering to PrEP has been shown to significantly reduce symptoms of anxiety and depression among young people vulnerable to acquiring HIV [135–137]. There is also emerging evidence that engagement in PrEP care can simultaneously promote greater engagement in screening and treatment for mental and behavioral health challenges, as well as screening and treatment for other health conditions, such as diabetes, hypertension, and tobacco use [138]. With this understanding, expanded PrEP care delivery and use could benefit both HIV prevention and mental health.

Conclusion

Our review has identified the following understandings about the intersection of mental health and HIV/AIDS:

(1) Mental health problems (ranging from distress to SMI) are elevated among people at-risk for HIV and those living with HIV. This risk is true across populations most affected by the epidemic in different regions of the world.
(2) Mental health problems contribute to HIV acquisition and poor outcomes along the HIV treatment continuum.
(3) HIV and the resulting chronic immune activation increase the risk to develop mental health problems.
(4) We have the necessary assessment (screening) tools and efficacious treatments to treat mental health problems among people living with and at risk for HIV. However, we need to prioritize mental health treatment, especially mental health treatment integrated into HIV care, with appropriate resources to address the current screening and treatment gap.
(5) Promising advances have been made integrating mental healthcare into HIV primary care (via task-shifting, stepped-care interventions, and other strategies).
(6) Some community and public health driven campaigns regarding HIV treatment and prevention may help reduce stigma and psychological distress.

Despite the significant challenges that mental health presents to HIV prevention and treatment, there are many important and unmet opportunities to integrate mental healthcare with HIV care. Initiatives like PEPFAR have helped countries around the world dramatically expand HIV care, and the concomitant strengthening of their healthcare systems has offered substantial benefits to wider healthcare delivery. Further integration of mental health screening and care into this infrastructure would not only strengthen HIV prevention and care outcomes, but it would additionally improve global access to mental healthcare. Seizing these opportunities will be crucial if we are to further 'bend the curve' of the HIV epidemic and eventually find an end to AIDS. On a very fundamental and basic level, there can be no health, without mental health.

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Conflicts of interest

There are no conflicts of interest.

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