LOS ANGELES COUNTY
COMMISSION ON HIV

AGENDA FOR THE **VIRTUAL** MEETING OF THE

STANDARDS AND BEST PRACTICES COMMITTEE

TUESDAY, APRIL 6, 2021, 10:00 AM – 12:00 PM

https://tinyurl.com/49pkxrhz

or Dial

1-415-655-0001

Event Number/Access code: 145 676 4167

(213) 738-2816 / Fax (213) 637-4748

HIVComm@lachiv.org http://hiv.lacounty.gov

Standards and Best Practices (SBP) Committee Members			
Erika Davies *Co-Chair*	Kevin Stalter *Co-Chair*	Miguel Alvarez, *Alternate*	Pamela Coffey *(Reba Stevens, Alternate)*
Wendy Garland, MPH	Grissel Granados, MSW	Thomas Green	Paul Nash,PhD, CPsychol AFBPsS FHEA
Katja Nelson, MPP	Joshua Ray (Eduardo Martinez, *Alternate*)	Harold Glenn San Agustin, MD	Justin Valero, MA
Ernest Walker, MPH	Amiya Wilson		
QUORUM: 8			

AGENDA POSTED: March 31, 2021

ATTENTION: Any person who seeks support or endorsement from the Commission on any official action may be subject to the provisions of Los Angeles County Code, Chapter 2.160 relating to lobbyists. Violation of the lobbyist ordinance may result in a fine and other penalties. For information, call (213) 974-1093.

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SUPPORTING DOCUMENTATION can be obtained at the Commission on HIV Website at: http://hiv.lacounty.gov. The Commission Offices are located in Metroplex Wilshire, one building west of the southwest corner of Wilshire and Normandie. Validated parking is available in the parking lot behind Metroplex, just south of Wilshire, on the west side of Normandie.

NOTES on AGENDA SCHEDULING, TIMING, POSTED and ACTUAL TIMES, TIME ALLOTMENTS, and AGENDA ORDER: Because time allotments for discussions and decision-making regarding business before the Commission's standing committees cannot always be predicted precisely, posted times for items on the meeting

agenda may vary significantly from either the actual time devoted to the item or the actual, ultimate order in which it was addressed on the agenda. Likewise, stakeholders may propose adjusting the order of various items at the commencement of the committee meeting (Approval of the Agenda), or times may be adjusted and/or modified, at the co-chairs' discretion, during the course of the meeting.

If a stakeholder is interested in joining the meeting to keep abreast of or participate in consideration of a specific agenda item, the Commission suggests that the stakeholder plan on attending the full meeting in case the agenda order is modified or timing of the items is altered. All Commission committees make every effort to place items that they are aware involve external stakeholders at the top of the agenda in order to address and resolve those issues more quickly and release visiting participants from the obligation of staying for the full meeting. External stakeholders who would like to participate in the deliberation of discussion of an a posted agenda item, but who may only be able to attend for a short time during a limited window of opportunity, may call the Commission's Executive Director in advance of the meeting to see if the scheduled agenda order can be adjusted accordingly. Commission leadership and staff will make every effort to accommodate reasonable scheduling and timing requests - from members or other stakeholders - within the limitations and requirements of other possible constraints.

Call to Order, Introductions, Conflict of Interest Statements 10:00 AM – 10:03 AM

I. ADMINISTRATIVE MATTERS 10:03 AM – 10:07 AM

1. Approval of Agenda **MOTION #1**

2. Approval of Meeting Minutes **MOTION #2**

II. PUBLIC COMMENT 10:07 AM – 10:10 AM

3. Opportunity for members of the public to address the Commission on items of interest that are within the jurisdiction of the Commission

III. COMMITTEE NEW BUSINESS ITEMS 10:10 AM – 10:15 AM

4. Opportunity for Commission members to recommend new business items for the full body or a committee level discussion on non-agendized Matters not posted on the agenda, to be discussed and (if requested) placed on the agenda for action at a future meeting, or matters requiring immediate action because of an emergency situation, or where the need to take action arose subsequent to the posting of the agenda.

IV. REPORTS

5. Executive Director/Staff Report 10:15 AM – 10:20 AM
- a. Commission and Committee Updates
- b. Ending the HIV Epidemic

6. Co-Chair Report 10:20 AM – 11:00 AM
- a. Committee Member Introductions/Getting to Know You
- b. "So, You Want to Talk about Race" by I. Oluo Reading Activity"
  - Excerpt selected by Co-Chairs from Chapter 1.
- c. 2021 Workplan

7. Division of HIV & STD Programs (DHSP) Report 11:00 AM – 11:15 AM
   a. Childcare & Language Services Provider Survey

V. DISCUSSION ITEMS

8. Substance Abuse, Transitional Housing 11:15 AM – 11:45 AM
   a. Background and Allocations Review
   b. Current Services Provided | Agency Presentations (Safe Refuge and Tarzana Treatment Centers)

VI. NEXT STEPS 11:45 AM – 11:55 AM

9. Task/Assignments Recap

10. Agenda development for the next meeting

VI. ANNOUNCEMENTS 11:55 AM – 12:00 PM

11. Opportunity for members of the public and the committee to make announcements

VII. ADJOURNMENT 12:00 PM

12. Adjournment for the virtual meeting of April 6, 2021

PROPOSED MOTIONS	
MOTION #1	**Approve the Agenda Order, as presented or revised.**
MOTION #2	**Approve the Standards and Best Practices Committee minutes, as presented or revised.**

LOS ANGELES COUNTY
COMMISSION ON HIV

3530 Wilshire Boulevard, Suite 1140 • Los Angeles, CA 90010 • TEL (213) 738-2816 • FAX (213) 637-4748
HIVCOMM@LACHIV.ORG • http://hiv.lacounty.gov • *VIRTUAL WEBEX MEETING*

Presence at virtual meetings is recorded based on the attendance roll call. Only members of the Commission on HIV are accorded voting privileges and must verbally acknowledge their attendance in order to vote.
Approved meeting minutes are available on the Commission's website; meeting recordings are available upon request.

STANDARDS AND BEST PRACTICES (SBP) COMMITTEE MEETING MINUTES

February 2, 2021

VMEMBERS PRESENT	MEMBERS PRESENT *(cont.)*	PUBLIC	COMM STAFF/ CONSULTANTS
Kevin Stalter, *Co-Chair*	Justin Valero, MA	Geneviéve Clavreul, RN, PhD	Cheryl Barrit, MPIA
Miguel Alvarez *(Alt.)*	Amiya Wilson	Amy Croft	Jane Nachazel-Ruck
Wendy Garland, MPH		LCDR Jose Antonio Ortiz, MPH	Sonja Wright, MS, Lac
Grissel Granados, MSW	**MEMBERS ABSENT**		
Thomas Green *(Alt.)*	Erika Davies, *Co-Chair*		**DHSP STAFF**
Paul Nash, PhD, CPsychol	Pamela Coffey		Lisa Klein, RN, MSN, CPHQ
Katja Nelson, MPP	Joshua Ray, RN/ Eduardo Martinez		
Harold Glenn San Agustin, MD	Ernest Walker, MPH		

*Some participants may not have been captured electronically. Attendance can be corrected by emailing the Commission.

CONTENTS OF COMMITTEE PACKET

1) **Cover Page**: Standards and Best Practices (SBP) Committee Virtual Meeting, *2/2/2021*
2) **Agenda**: Standards and Best Practices (SBP) Committee Meeting Agenda, *2/2/2021*
3) **Minutes**: Standards and Best Practices (SBP) Committee Meeting Minutes, *12/1/2020*
4) **Definition**: Service Standards, Ryan White HIV/AIDS Programs
5) **Tracker**: Service Standards Revision Date Tracker, *Ongoing*
6) **Table**: Standards and Best Practices Committee 2021 Work Plan, *Draft/For Review and Discussion Only, 1/21/2021*
7) **Report**: Division of HIV and STD Programs, Clinical Quality Management (CQM) Report, *December 2020*
8) **Recommendations**: Los Angeles County Commission on HIV, Standards and Best Practices Committee, Recommendations for Engaging Private Health Providers for A Stronger HIV Response, *Draft for Discussion Purposes Only, 1/26/2021*
9) **Standards**: Ryan White Program, Universal Service Standards, *Final Draft for Standards and Best Practices Committee Approval, 2/2/2021*
10) **Standards**: State of Pennsylvania, Service Standards, Child Care Services, *Effective July 2018*
11) **Standards**: South Carolina Ryan White, Part B Program Service Standards, *December 2018*
12) **Standards**: Childcare Standards of Care, *Draft – Updated 12/14/2020*

CALL TO ORDER-INTRODUCTIONS-CONFLICT OF INTEREST STATEMENTS: Mr. Stalter called the meeting to order at 10:07 am.

I. ADMINISTRATIVE MATTERS

1. APPROVAL OF AGENDA
MOTION #1: Approve the Agenda Order, as presented ***(Passed by Consensus)***.

2. APPROVAL OF MEETING MINUTES
MOTION #2: Approve the 12/1/2020 Standards and Best Practices (SBP) Committee Meeting Minutes, as presented ***(Passed by Consensus)***.

II. PUBLIC COMMENT

3. OPPORTUNITY FOR PUBLIC TO ADDRESS COMMISSION ON ITEMS OF INTEREST WITHIN COMMISSION JURISDICTION: There were no comments.

III. COMMITTEE NEW BUSINESS ITEMS

4. OPPORTUNITY FOR COMMISSIONERS TO RECOMMEND ITEMS FOR FUTURE AGENDAS, OR ITEMS REQUIRING IMMEDIATE ACTION DUE TO AN EMERGENCY, OR IF NEED FOR ACTION AROSE AFTER POSTING AGENDA: There were no items.

IV. REPORTS

5. EXECUTIVE DIRECTOR/STAFF REPORT
- Ms. Barrit reported Ms. Nachazel-Ruck has announced her retirement from Los Angeles County (LAC) at the end of March 2021. She was attending her last round of Commission/Committee meetings in February and will finish writing in March.
- There will be special recognition for Ms. Nachazel-Ruck at the 2/11/2021 Commission meeting. She staffed the Commission before it separated from DHSP, was first on staff when it did separate, and staffed the prevention/care integration. Mr. Stalter thanked her for her services over the many years in documenting the work of the Commission.
- Ms. Barrit requested patience as remaining staff pick up writing the minutes and capturing Committee discussions.
- The Planning, Priorities and Allocations (PP&A) Committee has asked staff to invite all Commission, Caucus, and Task Force members to join in PP&A's effort to lead the prevention planning for the Commission. As an integrated prevention and care planning body, the Commission needs to do a better job of full integration. Ideally, a separate Prevention Planning Work Group should not be necessary, but it is being used to jumpstart and strengthen the planning process. Founding Prevention Planning Work Group members are: Luckie Alexander Fuller; Miguel Martinez, MPH, MSW; and Maribel Ulloa.
- This will be a major undertaking for the Commission. Work Group meeting details should be emailed out early next week.
- The Operations and Executive Committees met 1/28/2021. They are working with HealthHIV, a national organization, to do an effectiveness assessment of the Commission. Included as part of the care and prevention planning bodies' integration in 2013 was a follow-up assessment of the integrated body's effectiveness. This is that long delayed assessment. HealthHIV staff will present at the 2/11/2021 Commission Meeting about the assessment surveys and expectations for participation.
- Ms. Barrit noted the Ryan White CARE Act requires Planning Councils (PCs) to address Priority Setting and Resource Allocations (PSRA) for care in their jurisdictions. Centers for Disease Control and Prevention (CDC) funding is usually addressed by a separate body. Care PCs may discuss related prevention issues without actual responsibility for prevention planning, but integrated planning improves outcomes. The Commission is one of the few PCs to have integrated planning.
- The Operations and Executive Committees also heard from LAC Human Relations Commission staff on training, coaching, skills building, and other Technical Assistance (TA) options to help Commissioners address systemic racism in the body's work, its commitment as an anti-racist organization, and conflict mediation. Human Relations Commission staff was also invited to the 2/11/2021 Commission Meeting to hear feedback on engaging the body in training and integrating the work into the meeting. It is expected the Commission will work with the Human Relations Commission for the next few years.

6. CO-CHAIR REPORT

a. New Committee Member Introductions
- Mr. Stalter broke the ice by introducing himself. He was diagnosed at 20 and has been HIV+ for 30+ years. He had some early close calls, but was now on medications that work well for him. He eventually became an advocate and joined the Commission some six years ago. He served as Operations Co-Chair before moving to SBP and becoming Co-Chair here.
- Dr. San Agustin said he was a physician of infectious diseases specializing in HIV. He practices in a Ryan White-funded community HIV clinic in East Hollywood. The clinic serves some 700 PLWH. He personally sees about 150 PLWH and also sees significant numbers of patients for Sexually Transmitted Diseases (STDs) and Hepatitis C.
- He was referred to the Commission by a mentor, former Commissioner Joseph Cadden, MD. He attended his first meeting in 2019 and immediately knew he wanted to participate. He plans to work in the HIV field for his full career.

- Dr. Nash is an Associate Professor of Gerontology, Aging, and Psychology, University of Southern California (USC). Most of his World Health Organization (WHO) work has focused on ageism, discrimination, prejudice, and how to disrupt it.
- Most recently, he has been talking with APLA Health and the LGBT Center on the impact of ageism, especially on the growing PLWH aging population. He has also participated in international research projects on ageism and HIV stigma. Last year, he provided some presentations to the Commission and was referred as a candidate. He found the Commission a fantastic organization and looked forward to the work.
- ➲ Next month a couple more SBP members will offer brief bios, including specialties, to help inform SBP discussion.

b. Service Standards Refresher

- Mr. Stalter noted while PP&A is responsible for the PSRA process, SBP's charge is to develop standards for the actual services including what training staff need to perform them. Once approved by the Commission, those service standards are submitted to DHSP which develops and monitors contracts to operationalize the service standards
- Ms. Barrit referred to the Ryan White definition document in the packet. The Universal Service Standards addressed later on the agenda provide minimum expectations for all services while standards for individual services pertain to the unique minimum requirements to provide that particular service. It might be said that standards provide a service map.
- In the past, standards commonly included outcome measures. The most recent guidance from the Health Resources and Services Administration (HRSA), however, is that development of outcome measures is under the purview of DHSP. That is consistent with DHSP's collection of data and its connection with providers to determine the most appropriate type of outcome measures to include as part of contract and monitoring.
- Service standards also help inform Requests for Proposals (RFPs) and strategies for Quality Improvement (QI).
- Mr. Stalter continued that the Commission seeks to ensure language is consumer-friendly and updated as needed. SBP has updated most active service standards over the last four years. Universal Standards are reviewed annually.
- ➲ Consider requesting a Technical Assistance (TA) service standards refresher training by Emily Gantz McKay.

c. Standards Revision Tracker

- Ms. Barrit noted the table in the packet which lists the last update for all service categories.
- All service categories prioritized by PP&A and referred to SBP for standards update were done excepting Childcare. That was on hold pending focus group information from DHSP.

d. 2021 Work Plan

- Mr. Stalter reviewed the Work Plan. Ms. Barrit noted it was a draft based on recommendations discussed to date.
- Mr. Valero asked about addressing telehealth. Ms. Barrit replied that one key reason to review the Universal Services Standards was to embed telehealth so it would be addressed as part of the menu of options for any service delivery. She noted that telehealth is not a separate Ryan White service category.
- ➲ Work Plan: Update Home-Based Case Management Standards, last updated in 2009, in response to internal DHSP discussions on enhancing and strengthening the program in advance of the expiration of its contract in about one year.
- ➲ Work Plan: Update Benefits Specialty, last updated in 2009, especially in regards to its relationship with the new Emergency Financial Assistance (EFA) Program Service Standards.
- ➲ Work Plan: Update Substance Use and Residential Treatment, last updated in 4/13/2017, per request.
- ➲ Work Plan: Review reflection of Telehealth services in Universal Service Standards, per request.
- ➲ Work Plan: Ms. Barrit will review older standards for possible updates in light of PP&A priorities and DHSP contracts.

7. DIVISION OF HIV AND STD PROGRAMS (DHSP) REPORT

- Ms. Garland noted some 80% of DHSP staff were still on COVID-19 response Disaster Services Worker (DSW) assignments. This is in addition to DPH commitment for everyone to work one day a week at a vaccine Point of Distribution (POD) site from January through February 2021.
- DHSP was finalizing childcare survey information and expected to forward it to the Commission in a week or so.

a. Quality Improvement Report

- Ms. Klein presented on the Clinical Quality Management (CQM) Report in the packet. She oversees the Ryan White CQM Program for DHSP and welcomed input on the new Report format. Like other Department of Public Health (DPH) employees, she and her entire team has been deployed to COVID-19 activities, e.g., vaccinations and contact tracing.
- The purpose of the newsletter is to provide stakeholders with updates and information on the CQM Program that spans the Eligible Metropolitan Area (EMA). HRSA Policy Clarification Notice (PCN) 15-02 requires recipients and sub-recipients of Ryan White Program (RWP) funds to have a CQM program that aims to improve the care, health outcomes, and satisfaction of PLWH. Required domains are: Infrastructure, Performance Measurement, and QI.

- Due to diversion of staff to COVID-19 activities, DHSP focused on essential CQM activities and updates via newsletter.
- The CQM Plan for RWP Years (YRs) 30-33 (calendar YRs 2020-2023) was just finalized and will be available shortly.
- HRSA wants the various RWP Parts to collaborate on QI. A major accomplishment for DHSP is its current participation as a subrecipient in the California Office of AIDS (OA) Part B CQM efforts and OA participating in DHSP's Part A efforts.
- Information on Performance Measures and graphs for Ambulatory Outpatient Medical (AOM), Medical Care Coordination (MCC), Benefit Specialty Services (BSS), Oral Health (OH) were in the provided Report. Data reflects some slight declines most likely related to the COVID-19 pandemic, e.g., fewer people were attending AOM appointments.
- Ms. Klein reviewed QI capacity building and Performance Measurement activities. MCC teams serve one of the hardest populations to reach and retain in care so the initial goal was to provide data to HIV providers to help them explore ways to increase engagement in care in this population.
- However, the COVID-19 pandemic hit locally shortly after the March 2020 kick-off of the Mission Possible QI Collaborative. Consequently, DHSP pivoted to a virtual format and re-prioritized the MCC goal to focus on how to best utilize telehealth services with clients to avoid losing PLWH clients during the pandemic. Attendance remained fairly stable across the six meetings that explored various aspects of telehealth with 111 attending the 11/18/2020 closing.
- The Grievance Management Program is also part of the unit's responsibility. It addressed 36 grievances in 2020. The table in the packet reflects service categories and types of grievances. AOM is the largest service category and draws the most grievances. Inappropriate or unprofessional behavior is the most common complaint.
- Staff turnover in the unit has been high the past few years so categories were being reviewed to ensure service and complaint categories are appropriate for particular issues. Unknown/Unstated and Other/Non-jurisdictional complaints reflect situations in which the complainant does not respond to follow-up calls, the complaint was about a provider outside DHSP's purview, or the person sought general information like how to find resources such as condoms.
- DHSP also sponsors a Los Angeles Regional Quality Group and participates in the continued California Regional Group which most recently was working on an Inititive regarding the unstably unhoused.
- DPH requires its programs to report Performance Counts annually, but it reduced DHSP measures to four because of the pandemic. The remaining measures are for the percentages respectively of PLWH countywide and in the RWP who are retained in medical care as well as the percentages of those population who are virally suppressed. Consistently, the RWP population does 20% to 30% better on these measures than the general LAC population of PLWH.
- In Ending the HIV Epidemic (EHE) activities, Linkage to HIV medical care (LTC) is highlighted as one of the six EHE indicators. It is calculated as the percentage of those diagnosed with HIV in a given year who have received medical care for their HIV infection within one month of diagnosis. This is also a central feature of the LAC EHE Plan.
- The goal is to improve LTC for all PLWH, but with special focus on those reflecting the greatest disparities: cisgender women, Black/African Americans, youth age 13-19, and Persons Who Inject Drugs (PWID). The national goal is 95% by 2025. The LAC LTC performance level has improved from 69.9% in 2017 to 85.7% in Quarter 1 of 2020.
- Ms. Granados asked if any Quality of Life (QOL) measures such as housing or mental health, as opposed to strictly biomedical markers, were being tracked. Ms. Klein replied RWP CQM measures do not include QOL, but different measures are tracked for specific programs that may include QOL measures.
- Ms. Garland added there was QOL information in utilization reports, but that team has not met for a year due to the pandemic. She was considering how to incorporate QOL data into the surveillance report to provide a broader picture of not just demographics but root causes such as housing. Ms. Granados thought it important for overall wellness.
- Ms. Granados also asked about any QI measures for prevention programs. Ms. Klein replied she only addresses RWP.
- Mr. Stalter noted several items related to engaging consumers better, e.g., through secret shoppers or Survey Monkey. He would also like to compare LAC data with other large EMAs. He noted the word graph highlights listening.

➲ Ms. Garland will follow-up on possible prevention and prevention/care crossover measures and related outcomes for a client who, e.g., may utilize AOM and some prevention services.

➲ Ms. Klein reported continued interaction with the Consumer Caucus including plans to forward this report and a request for additional feedback. She will ask Rebecca Cohen, MD, MPH about the source for the word graph.

➲ Ms. Garland will provide a distilled report from HRSA basic RWP national data by state and jurisdiction. Most recent data would be from 2019 because it takes HRSA time to collect and compile nationwide data.

➲ Provide as part of next Commission SBP Co-Chair report and continue as SBP meeting agenda item.

V. DISCUSSION ITEMS

8. ENGAGING PRIVATE HEALTH PLANS AND PROVIDERS

- Ms. Barrit referred to the document in the packet summarizing previous discussions and suggestions. Mr. Stalter added the previous CQM data reflected that the RWP was more effective in achieving desired outcomes. The purpose of this effort is to bring other providers up to the same standard of care in order to improve outcomes countywide.
- Ms. Barrit noted there was a need to clarify some of the systems barriers that have arisen with implementation of Emergency Financial Assistance (EFA), especially a perception that a client must give up their medical provider to use MCC. That suggests that the first small step might be to improve knowledge of the RWP system within the system itself.
- Mr. Stalter has experienced situations in which clients were unable to access services unless they switched physicians and sometimes even pharmacies. Obviously, non-RWP providers would not want to refer people for support services under that circumstance. Ms. Granados added this was a larger conversation. If a client from a non-RWP provider did use MCC while maintaining the original medical services, then there would be an issue with coordinating data.
- Ms. Barrit noted SBP recently revised, and the Commission approved, the non-Medical Case Management Services Standards. The revised iteration was to facilitate services for those individuals who may not need intensive support under MCC and are generally virally suppressed, but may need some level of case management for supportive services. That might be reviewed as possibly pertinent to the needs of the non-RWP population seeking wrap-around services.
- She encouraged considering the overall capacity of the RWP system as it stands now and in view of COVID-19 stresses.
- Mr. Stalter suggested the SBP and the Priorities, Planning and Allocations (PP&A) Committees work together to identify an appropriate medical home for those outside the RWP network who commonly bounce in and out of various wrap-around services. Perhaps more funding should be devoted to establishing and supporting medical home environments.
- Mr. Valero said access to wrap-around RWP services in the San Gabriel and San Fernando Valleys is generally through psychosocial services. Advocacy through them could be very helpful as many people are unaware RWP wrap-around services exist. Increased psychosocial service funding could help those programs advise more people of options.

➲ Elevate to Executive Committee: Discussion on how to establish medical home environments for non-RWP clients.

9. UNIVERSAL SERVICE STANDARDS

- Ms. Barrit noted the public comment period ended at the end of January. Only one comment was received. It reiterated the importance of client confidentiality which was already included in the standards.
- Staff provided some updates to the Patient Bill of Rights based on feedback from the Consumer Caucus.

MOTION #3: Approve the updated Universal Service Standards, as presented, and forward to the February Executive Committee for approval to forward to the March Commission meeting for final approval ***(Passed by Consensus)***.

10. CHILDCARE SERVICES STANDARDS UPDATES

- Ms. Barrit reported SBP continued to pause revisions to wait for the DHSP survey information.
- Meanwhile, she was requested to provide other EMA approaches to informal childcare after County Counsel advised LAC restricted services to licensed providers. That material was in the packet. In general, informal childcare in other EMAs requires working with a third party; the client signs a liability release form protecting the client, the provider, and the RWP; and requires the subcontractor to maintain good documentation that payment is not made to the client.
- Ms. Barrit contacted Emily Gantz McKay on the matter. She replied most EMAs have restrictions similar to LAC.

➲ SBP will review informal childcare options again after review of the included documents.

VI. NEXT STEPS

11. TASK/ASSIGNMENTS RECAP: There were no additional items.

12. AGENDA DEVELOPMENT FOR NEXT MEETING: There were no additional items.

VII. ANNOUNCEMENTS

13. OPPORTUNITY FOR PUBLIC AND COMMITTEE TO MAKE ANNOUNCEMENTS: There were no announcements.

VIII. ADJOURNMENT

14. ADJOURNMENT: The meeting adjourned at 11:55 am.

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COMMISSION ON HIV

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STANDARDS AND BEST PRACTICES (SBP) COMMITTEE MEETING MINUTES

March 2, 2021

VMEMBERS PRESENT	MEMBERS PRESENT *(cont.)*	PUBLIC	COMM STAFF/ CONSULTANTS
Erika Davis, *Co-Chair*	Joshua Ray, RN	Anthony Corona	Cheryl Barrit, MPIA
Kevin Stalter, *Co-Chair*	Eduardo Martinez (Alt.)	La Kesha Farmer	Jane Nachazel-Ruck
Miguel Alvarez *(Alt.)*	Harold Glenn San Agustin, MD	Ebony Gudger	Carolyn Echols-Watson
Pamela Coffey	Ernest Walker, MPH	LCDR Jose Antonio Ortiz, MPH	**DHSP STAFF**
Wendy Garland, MPH	Amiya Wilson	Elizabeth Vera	Lisa Klein, RN, MSN, CPHQ
Grissel Granados, MSW	**MEMBERS ABSENT**		
Thomas Green *(Alt.)*	Justin Valero, MA		
Paul Nash, PhD, CPsychol			
Katja Nelson, MPP			

*Some participants may not have been captured electronically. Attendance can be corrected by emailing the Commission.

CONTENTS OF COMMITTEE PACKET

1) **Cover Page**: Standards and Best Practices (SBP) Committee Virtual Meeting, *3/2/2021*
2) **Agenda**: Standards and Best Practices (SBP) Committee Meeting Agenda, *3/2/2021*
3) **Tracker**: Service Standards Revision Date Tracker, *Ongoing*
4) **Table**: Standards and Best Practices Committee 2021 Work Plan, *Updated 2/18/2021, Ongoing*
5) **Document:** Service Standards Links for Selected Categories and Service Definitions
6) **Recommendations**: Los Angeles County Commission on HIV, Standards and Best Practices Committee, Recommendations for Engaging Private Health Providers for A Stronger HIV Response, *Draft for Discussion Purposes Only, Updated 2/18/2021*

CALL TO ORDER-INTRODUCTIONS-CONFLICT OF INTEREST STATEMENTS: Mr. Stalter called the meeting to order at 10:05 am.

I. ADMINISTRATIVE MATTERS

1. APPROVAL OF AGENDA
MOTION #1: Approve the Agenda Order, as presented ***(Passed by Consensus)***.

2. APPROVAL OF MEETING MINUTES
MOTION #2: Approve the 01/05/2021 Standards and Best Practices (SBP) Committee Meeting Minutes, as presented ***(Passed by Consensus)***.

II. PUBLIC COMMENT

3. OPPORTUNITY FOR PUBLIC TO ADDRESS COMMISSION ON ITEMS OF INTEREST WITHIN COMMISSION JURISDICTION: There were no comments.

III. COMMITTEE NEW BUSINESS ITEMS

4. OPPORTUNITY FOR COMMISSIONERS TO RECOMMEND ITEMS FOR FUTURE AGENDAS, OR ITEMS REQUIRING IMMEDIATE ACTION DUE TO AN EMERGENCY, OR IF NEED FOR ACTION AROSE AFTER POSTING AGENDA: There were no items.

IV. REPORTS

5. EXECUTIVE DIRECTOR/STAFF REPORT

- Cheryl Barrit reminded members to complete the Health HIV member survey. The survey is to assess the planning bodies effectiveness and the results will be used for technical assistance and other member support efforts.
- Los Angeles County Human Relations Commission will train the Commission on conducting productive conversations on racism and other "isms". The first training is March 11, 2021 at the full Commission meeting. The Human Relations Commission will integrate the reading "So You Want to Talk About Race" into the Commission training. Members wanting a book are to contact Dawn McClendon.
- It was noted the intent of Committees reading the book is to encourage conversation about race that advances meaningful decisions that sustain social and racial justice in HIV care. The specifics of the logistics of book reading at the Committee level are still to be determined.
- The Commission prepared and have out for review a letter to local and state officials regarding People Living with HIV (PLWH) and the COVID 19 vaccine. The deadline for feedback to staff is March 2, 2021.

6. CO-CHAIR REPORT

a. New Committee Member Introductions/Getting to Know You

- Kevin Stalter invited Committee members/Commissioners Grissel Granados, Katja Nelson, and Paul Nash to introduce themselves to the group.
- G. Granados noted that she is a proud mom to a little boy. She is the HIV Prevention Manager at Children's Hospital Los Angeles (CHLA). She has been a Commissioner since 2013, the year the County merged the HIV prevention and care planning bodies of the County. She served on the legacy Prevention Planning Group. She likes cats and chocolates. She is a former Commission and SBP Co-Chair and has led various workgroups in the Commission.
- K. Nelson is the Local Affairs Specialist, Government Affairs Division at APLA Health. She has been with APLA for six years. She likes dogs and chocolates. Her entry into HIV work started with participating in AIDS Walks in high school and noted that she has always been drawn to understanding politics/political science. She attended graduate school at UCLA and was involved in an HIV related project. She loves languages and speaks Spanish and Russian. She is also the Public Policy Co-Chair and SBP is her secondary Committee assignment.
- P. Nash, PhD, is a new member of the Commission and joined during the COVID-19 pandemic in 2020. He is from the United Kingdom and has been in the U.S. for 3 years. He is a gerontologist and his research in the UK in sexual health in nursing homes sparked interest in HIV work. He has been working on seminal research/studies with Dr. Steven Karpiak, Associate Director for Research at the AIDS Community Research Initiative of America's (ACRIA), on HIV and older adults. He is an avid cyclist and has been a part of the AIDS Life Cycle fundraising and awareness campaign. He is member of the Aging Task Force as well.
- ➲ Next month Wendy Garland, Thomas Green, and Miguel Alvarez will share their stories as part of the Getting to Know You activity.

b. Standards Revision Tracker

- Ms. Barrit noted the table in the packet which lists the last update for all service categories.

c. 2021 Work Plan

- Mr. Stalter reviewed the Work Plan. The following service standards have been added for review/update 2021: 1) Home-based Case Management (HBCM); 2) Benefits Specialty (BS); 3) Substance Use and Residential Treatment (SURT).

7. DIVISION OF HIV AND STD PROGRAMS (DHSP) REPORT

a. Childcare & Language Services Provider Survey

- DHSP was finalizing childcare survey information and expected to forward it to the Commission in a week or so. The response rate from the contracted providers was low and DHSP staff are working with providers to get more responses. Ms. Garland noted that she hopes to provide a summary of the survey to the Committee in April.

V. DISCUSSION ITEMS

The Committee discussed in ideas on how to tackle the review and refinement of service standards for Benefits Specialty, Home Based Case Management, and Substance Use and Residential Treatment. Ms. Garland noted that DHSP has service utilization data available for 2019 and 2020 that the Committee may review to help with the service standards update. The data for 2019, especially for BS, may be more representative of the needs because of its pre-COVID data time frame.

8. Benefits Specialty

- Ms. Davies noted that updating the Benefits Specialty standards should be updated as soon as possible due to the greater need for the service based on recent experience on the launch of the Emergency Financial Assistance and the impact of COVID-19 on the community. She can share insights as a provider with regards to BS and HBCM.
- **Process ideas discussed:** review what has worked, what has not; understand the needs of the PLWH; seek input from subject matter experts; review lessons learned about the BS service from the last 10 years; what is the best way for PLWH to access public and private health insurance and other benefits/programs; and seek input from clients who have used the service and understand barriers to accessing BS.

9. Home-based Case Management

- It is important to review and update the HBCM standards especially with the aging HIV population. Collaborate with the Aging Task Force shape the HBCM standards. Explore peer-based models for providing HBCM services.
- Ms. Garland noted that DHSP is currently having internal discussions on HBCM for older adults.

10. Substance Use and Residential Treatment

- Ms. Nelson noted that APLA can offer support via subject matter expertise for the SURT standards and other services as well.
- Invite Dr. Steve Shoptaw to provide comments on the document. Use journal article shared by Dr. Harold Glenn San Agustin to help inform the Committee's deliberations.
- Drug Medi-Cal guidance has evolved, and the Committee should align the standards with new treatment/service guidelines.

VI. NEXT STEPS

11. TASK/ASSIGNMENTS RECAP:

- Staff will work with Ms. Garland to schedule service utilization data presentation for BS, HBCM, and SUTR.
- Update the 2021 SBP Work Plan to show that the Committee will tackle SUTR first, followed by BS and HBCM.
- Begin review of SUTR at the April meeting.
- Next month Wendy Garland, Thomas Green, and Miguel Alvarez will share their stories as part of the Getting to Know You activity.

12. AGENDA DEVELOPMENT FOR NEXT MEETING: There were no additional items.

VII. ANNOUNCEMENTS

13. OPPORTUNITY FOR PUBLIC AND COMMITTEE TO MAKE ANNOUNCEMENTS: There were no announcements.

VIII. ADJOURNMENT

14. ADJOURNMENT: The meeting adjourned at 10:56 am.

LOS ANGELES COUNTY COMMISSION ON HIV

SERVICE STANDARDS REVISION DATE TRACKER as of 3/16/2021

	Standard Title	DHSP Program(s)	Date of Last Standard Revision	Program Currently Funded	Contract Expiration Date	Notes
1	AIDS Drug Assistance Program (ADAP) Enrollment		2009			ADAP contracts directly with agencies
Non-Medical Case Management						
2	Benefits Specialty	Benefits Specialty Services	2009	X	February 28, 2022	
3	Case Management, Transitional – Youth	Transitional Case Management-Youth	4/13/2017		March 31, 2020	Last funded two providers for this service through March 31, 2020
4	Case Management, Transitional – Incarcerated/Post Release	Transitional Case Management-Jails	4/13/2017	X	February 28, 2022	
5	Non-Medical Case Management	Linkage Case Management	12/12/2019		March 31, 2017	No longer funded.
6	Childcare		2009; currently being updated; latest draft revision date 12/14/2020			Last funded in 2009.
7	Emergency Financial Assistance Program (EFA)	EFA	6/11/2020	X	February 28, 2022	

8	Home-Based Case Management	Home-Based Case Management	2009	X	June 30, 2021	Contracts to be renewed for an additional 12 months in June 2021.
9	Hospice		2009			
10	Housing, Temporary: • Hotel/motel and meal vouchers, • Emergency shelter programs, • Transitional housing, • Income-based Rental Assistance, • Residential Care Facility for the Chronically Ill, and • Transitional Residential Care Facility	• Transitional Residential Care facilities (TRCF) • Residential Care facilities for the Chronically Ill (RCFCI) • Substance Use Transitional Housing (SUTH)	2/8/2018	X	February 28, 2022	
11	Housing, Permanent Supportive	Permanent Supportive Housing	2/8/2018		N/A	No contracts in permanent housing only temporary and worked with other entities for permanent housing (eg. DHS Housing for Health MOU).
12	Language Interpretation		2009		February 28, 2021	Contract expired 2-28-21, no response from provider need to solicit for new services again.
13	Legal	Legal Services	7/12/2018	X	August 24, 2024	New provider started December 2020
14	Medical Care Coordination	Medical Care Coordination	2/14/2019	X	February 28, 2022	New contracts started 3-1-19
15	Mental Health, Psychiatry, and Psychotherapy	Mental Health	2009	X	February 28, 2022	New FFS model started 8-1-17

16	Nutrition Support	• Food Bank • Home Delivery	2009	X	February 28, 2022	
17	Oral Health • Practice Guidelines for Treatment of HIV Patients in General Dentistry	• General Oral Health • Specialty Oral Health	2009 2015	X	February 28, 2022	
18	Outreach		2009		N/A	Never funded as a stand-alone contract. but has been part of Health Education/Risk Reduction. Linkage and Re-engagement Program (LRP) and partner services were supported as HRSA Part A Outreach Services. No contract for LRP and partner services because these activities are conducted by DHSP staff.
19	Peer Support		2009; integrated in Psychosocial Support 9/10/2020		October 15, 2009	No longer funded. Terminated due to state cuts back in 2009.
20	Permanency Planning		2009		February 28, 2010	No longer funded. It can be addressed by either BSS or Legal. Merged under legal contract in 2010.
21	Prevention Services: • Assessment; • HIV/STD Testing and Retesting; • Linkage to HIV Medical Care and Biomedical Prevention;		6/14/2018		HERR; 06/30/2021 VP: 12/31/2022 HIV Testing: 12/31 2022	"Take Me Home" online self HIV testing kits distributed through MOU with NASTAD. Self HIV tests kits also pending distribution through HIV/STD Testing contracts and with non-traditional community partners through MOUs.

	• Referral and Linkages to Non-biomedical Prevention; • Retention and Adherence to Medical Care, ART; and • Other Prevention Services				STD screening and Treatment: 12/31/2022 BIomedical: 6/30/2021	Currently evaluating extension of Biomedical contracts
22	Psychosocial Support		9/10/2020		August 31, 2017	No longer funded
23	Referral Services		2009		N/A	Not funded as a standalone service, included under various modalities
24	Residential Care and Housing		2009; integrated in Temporary and Permanent Supportive Housing 2/8/2018		(See #9 and 10)	
25	Skilled Nursing Facilities		2009		February 28, 2010	No longer funded replaced with RCFCI and TRCF- see under #24
26	Substance Use and Residential Treatment		4/13/2017		February 28, 2019	No longer funded. Funded by SAPC
27	Transportation		2009	X	February 28, 2023	New contracts began 6-1-20 and 9-1-20
28	Treatment Education		2009		October 15, 2009	No longer funded. Terminated due to state cuts. Activities incorporated into other programs (e.g. U=U social marketing)
29	Universal Standards		9/12/2019; currently being updated; latest draft		N/A	Not a program – standards that apply to all services

			revision date 12/16/2020 released for public comments			

LOS ANGELES COUNTY
COMMISSION ON HIV

Standards & Best Practices Committee
Standards of Care

- Service standards are written for service providers to follow
- Service standards establish the minimal level of service or care that a Ryan White funded agency or provider may offer
- Service standards are essential in defining and ensuring consistent quality care is offered to all clients
- Service standards serve as a benchmark by which services are monitored and contracts are developed
- Service standards define the main components/activities of a service category
- Service standards do not include guidance on clinical or agency operations

Retrieved from https://targethiv.org/library/service-standards-guidance-ryan-white-hivaids-program-granteesplanning-bodies. December 2015.

Standards of Care Review
Guiding Questions

1. Are the standards up-to-date and consistent with national standards of high quality HIV and STD prevention services?

2. Are the standards reasonable and achievable for providers?

3. Will the services meet consumer needs? Are the proposed standards client-centered?

4. What are the important outcomes we expect for people receiving this service? How can we measure whether or not the service is working for them?

5. Is there anything missing from the standards related to HIV prevention and care?

6. Is there anything missing in regard to other topics such as reducing stigma, social determinants of health, immigration issues, support around insurance and housing, etc.?

7. Are the references still relevant?

Los Angeles County Commission on HIV | Standards and Best Practices Committee
Contracted providers for selected service categories | for information only and consideration of potential reviewers

Case Management, Home-Based	1. APLA Health & Wellness 2. Dignity Health (dba St. Mary Medical Center) Minority AIDS Project 3. Tarzana Treatment Centers, Inc.
Benefits Specialty	1. APLA Health & Wellness 2. City of Long Beach, Dept of Health & Human Services 3. Dignity Health (dba St. Mary Medical Center) 4. East Valley Community Health Center, Inc. 5. JWCH Institute, Inc. 6. Minority AIDS Project Northeast Valley Health Corporation 7. Tarzana Treatment Centers, Inc.
Substance Abuse, Transitional Housing	Safe Refuge
Substance Abuse, Transitional Housing (meth)	Tarzana Treatment Centers, Inc.

STANDARDS AND BEST PRACTICES COMMITTEE 2021 WORK PLAN
Updated 3/10/21

Co-Chairs: Erika Davies & Kevin Stalter		
Approval Date: 3/1/21	**Revision Dates: 3/10/21**	
Purpose of Work Plan: To focus and prioritize key activities for COH Committees and subgroups for 2021. **Prioritization Criteria:** Select activities that 1) represent the core functions of the COH; 2) advance the goals of the local Ending the HIV Epidemic (EHE) Plan; and 3) align with COH staff and member capacities and time commitment; 4) ongoing COVID public health emergency response and recovery priorities.		
#	**TASK/ACTIVITY**	**TARGET COMPLETION DATE**
1	Review BAAC and ATF charge and implement recommendations best aligned with the purpose and capacity of the Commission	Start Jan/Ongoing
~~2~~	~~Complete Universal service standards.~~ COMPLETED	~~March-Executive Committee April- COH~~
3	Complete Childcare service standards. Waiting for DHSP on provider survey results/summary.	May
4	Recommendations on how to engage with private health plans and providers	On hold
5	Update Substance use outpatient and residential treatment service standards	July
6	Update Benefits Specialty service standards	August
7	Update Home-based Case Management service standards	September

DHSP Provider Survey: Background

- In an effort to better understand the needs of community members and support the services being offered by Ryan White providers, DHSP distributed a short online survey regarding the **childcare, interpretation** and **translation** needs of clients
- The survey consisted of 7-10 questions and was estimated to take 5-10 minutes
- The link was emailed to 42 Ryan White agencies on 12/16/2020
- 16 of the 42 agencies responded (38%) at this time
- The link was emailed again to agencies on 3/02/2021 to ask for participation
- An additional 8 agencies responded
- **Overall response rate was a total of 24/42 (57%)**

Provider Survey: Childcare and Translation Needs

24 out of 42 RW agencies responded (57%)

- AIDS Health Care Foundation
- APLA
- Bienestar
- Children's Hospital Los Angeles
- City of Long Beach
- DHS Harbor UCLA Medical Center
- DHS High Desert Health
- DHS Hubert Humphrey – Main Street Clinic
- DHS Long Beach Comprehensive Health Center
- DHS Olive View, UCLA
- DHS Rand Schrader Clinic
- East Valley Community Health Center
- El Proyecto del Barrio
- JWCH
- Oasis Clinic
- Northeast Valley Community Clinic
- Saban Community Clinic
- St. John's Well Child and Family Center
- St. Mary's Care Center
- Tarzana
- T.H.E. Clinic Inc
- UCLA Care Clinic
- UCLA Peds/LAFAN
- Watts Health Care Corporation

Top 5 RW Agencies with Highest Proportion of Female Clients of Childbearing Age

Agency	Total RW Females Served, Aged 15-44 (%) - March 2019-February 2020
Salvation Army Alegria	17 (60.7%)
MCA Clinic	230 (49.6%)
Center for Health Justice	18 (18.8%)
Children's Hospital, LA	8 (16.7%)
Watts HealthCare Corporation	19 (9.1%)

*Highlighted color denotes agencies that completed and submitted the Provider Survey

Provider Survey: Childcare Needs

- None of the agencies who responded to the survey currently provide childcare services
- 11/24 (46%) identified a need for childcare
  - 9/11 (82%) said 25% or less of their clients needed childcare about 2 days/week

Would you consider applying for childcare if DHSP offered it?

- YES: 11/24 (46%)
  - 5 agencies who did NOT identify a need for childcare would apply anyway
- NO: 13/24 (54%)
  - 4 agencies who stated they needed childcare would NOT apply for funding
  - Main reasons: Don't have the client need, **lack of space**, no females of childbearing age served

Provider Survey: Childcare Needs

County of Los Angeles Public Health

Agency	Need Childcare? Yes/No	Consider Childcare if DHSP funded?	Total RW Females Served, Aged 15-44 (%) - March 2019-February 2020
AIDS Healthcare Foundation	No	No	163 (4.3%)
APLA	No	Yes	61 (2.3%)
Bienestar	No	Yes	2 (2.5%)
Children's Hospital	No	Yes	8 (16.7%)
DHS Harbor UCLA	No	No	56 (6.7%)
DHS High Desert	No	Yes	7 (4.8%)
DHS Long Beach	No	No	4 (2.5%)
East Valley Community Clinic	No	No	21 (4.8%)
JWCH	No	Yes	34 (3.7%)
Saban Community Clinic	No	No	---
St. Mary's Care Center	No	No	41 (3.9%)
T.H.E. Clinic	No	No	13 (6.3%)
UCLA CARE Clinic	No	No	16 (2.4%)

Provider Survey: Childcare Needs

County of Los Angeles Public Health

Agency	Need Childcare? Yes/No	Consider Childcare if DHSP funded?	Total RW Females Served, Aged 15-44 (%) - March 2019-February 2020
City of Long Beach	Yes	No	10 (4.9%)
DHS Hubert Humphrey – Main Clinic	Yes	Yes	18 (5.0%)
DHS Rand Schrader	Yes	Yes	147 (7.9%)
DHS Olive View UCLA	Yes	Yes	46 (8.5%)
El Proyecto Del Barrio	Yes	Yes	10 (4.7%)
MCA Clinic	Yes	No	230 (49.6%)
Northeast Valley Health Corp	Yes	No	42 (5.9%)
OASIS Clinic	Yes	No	27 (7.6%)
St John's	Yes	Yes	6 (6.9%)
Tarzana	Yes	Yes	19 (3.3%)
Watts Health Care Corporation	Yes	Yes	19 (9.1%)

Top 5 RW Agencies with Highest Proportion of Non-English Speaking Clients

Agency	Total Non English Speakers (%) - March 2019-February 2020
Bienestar	69 (87.3%)
El Proyecto Del Barrio	146 (68.2%)
AltaMed	750 (59.3%)
Rand Schrader	1030 (55.7%)
MCA Clinic	251 (54.1%)

*Highlighted color denotes agencies that completed and submitted the Provider Survey

Provider Survey: Translation Needs

- **21/24 (88%) currently offer translation/interpretation service**
- Those that offered translation/interpretation services noted they use:
  - *"A translation/interpretation service is used for the whole company. When we had PALS it was more convenient."*
  - *"Staff are bilingual and so can meet most language needs on their own."*
  - *"We use a telephone translation service or staff members when needed. Providers are never really sure that patients are understanding medication instructions or are able to answer all patient questions. Medical interpretation would also be a plus for deaf clients. In the past, GLAAD Case Managers would meet clients for appointments and were able to explain medication regimens, ask questions and assist with other client needs."*
  - *"We have traditionally used PALS for languages other than Spanish."*
  - *"We utilize facility resources for on site and telephonic interpretation or I-pad for sign language."*
- **Only 9/24 (38%) identified a need for translation services among 25-50% (avg) of their clients**
  - Languages requested: Spanish, Cantonese, Mandarin, Farsi, Tagalog, French

Provider Survey: Interpretation/Translation

County of Los Angeles Public Health

Agency	Need Interpretation?	Need Translation?	Total Non English Speakers (%) - March 2019-February 2020
AIDS Healthcare Foundation	No	No	1495 (22.8%)
APLA	No	No	579 (22.5%)
Bienestar	No	Yes	69 (87.3%)
Children's Hospital	No	No	3 (6.3%)
DHS Harbor UCLA	No	No	342 (40.6%)
DHS High Desert	No	Yes	20 (13.7%)
DHS Hubert Humphrey – Main Clinic	No	No	130 (36.6%)
DHS Long Beach	No	No	38 (23.3%)
DHS Olive View UCLA	No	No	249 (46.2%)
Northeast Valley Health Corp	No	No	313 (43.9%)
Saban Community Clinic	No	Yes	---
St John's	No	No	46 (52.9%)
St. Mary's Care Center	No	Yes	197 (19.1%)
Tarzana	No	No	53 (9.2%)
UCLA Care Clinic	No	Yes	79 (11.9%)

Provider Survey: Interpretation/Translation

Agency	Need Interpretation?	Need Translation?	Total Non English Speakers (%) - March 2019-February 2020
MCA Clinic	Yes	Yes	251 (54.1%)
OASIS Clinic	Yes	Yes	83 (23.3%)
City of Long Beach	Yes	Yes	36 (17.7%)
DHS Rand Schrader	Yes	No	1030 (55.6%)
East Valley Community Clinic	Yes	Yes	136 (30.9%)
El Proyecto Del Barrio	Yes	Yes	146 (68.2%)
JWCH	Yes	No	242 (25.9%)
T.H.E. Clinic	Yes	Yes	64 (31.4%)
Watts Health Care Corporation	Yes	Yes	91 (43.8%)

Listening Sessions: Interpretation Needs

Oral health services was brought up only in the LAFAN group:

- For oral health appointments, the majority of clients indicated not having access to interpretation services during their visits
- They indicated there are sometimes dental assistants that are bilingual who would quickly explain the procedures and/or interpret for the dentist, but this was not always available.
- Everyone confirmed that phone interpretation was not available during their dental visit.

“I did not know they were going to pull my tooth; no one was able to explain to me what was going to happen.”

Listening Sessions: Interpretation Needs

- For mental health services, a couple of participants indicated having used phone interpretation services.
  - One client stated they were satisfied with the service because they had built a relationship with the interpreter who was always the same one.
  - Another client did not feel that phone interpretation worked for this type of service because the flow of the conversation was lost, when they needed to pause for the interpreter. They also felt that the “feelings” were never able to be conveyed.
  - In the other groups, everyone felt that mental health should be provided in Spanish and not through an interpreter.

Listening Sessions: Translation Needs

All the participants indicated needing translation services that included:

- Translating forms
- Getting assistance to fill out forms/applications
- Having all documents needed to be singed (consent forms, etc.) in Spanish
- Clients reported paying someone to translate documents

“I helped a friend fill out an application as much as I could, but when they submitted it, their application was denied because information was missing.”

Listening Sessions Summary

- ✓ Clients indicated there is a need for services to be offered in Spanish as a preference.
- ✓ Clients prefer to have interpreters in person and not via the phone.
- ✓ Interpreters need to be professional so that the information shared is accurate
- ✓ There is a need for interpreters for oral health services
- ✓ There is a need for translation services

Provider Survey: COVID- 19 Impact

How has COVID-19 impacted your services?

18/24 (75%) stated there were **no major disruptions** to their services. Comments from the other 6 providers who noted some impact included:

- *"Phone translation has increased the time for patient care"*
- *"More tele-health services resulting in less childcare issues"*
- *"Only change is that most services for patients are now completed on the telephone."*
- *"Parents now have canceled visits due to restrictions on number of participants during the visit. Not having an option for additional members, rather than the patient has limited the drive to continue care."*
- *"Having onsite childcare and translation services will positively impact adherence to medical appointments."*
- *"The only change we have had is that we no longer have an in-person interpreter in our clinic. These are all done over the phone with staff from our Culture and Linguistics Department here at LAC+USC. We do have staff who are bilingual and help with interpretation."*

Summary/Key Take Aways

- Fewer than half of the 24 providers who responded to the survey stated they needed childcare services and just over half indicated they would not apply for additional funding if available (58%). Most also indicated it was a need only 1-2 days a week.
- Most providers offer interpretation/translation services (88%) and only 33% indicated an additional need for these services. However, the comments implied that while these services may be available, they could be improved especially for languages other than Spanish (e.g. Cantonese, Mandarin, Farsi, Tagalog, French).
- Three of out four of the providers (75%) reported no huge disruptions to their services from COVID-19. The main barrier or change noted was that services have moved to tele-health.
- Only 57% of the 42 DHSP-funded agencies responded to the survey so results may not represent the experience of all contracted agencies.

RYAN WHITE HIV SUBSTANCE USE DISORDER - RESIDENTIAL HOUSING SERVICES

Draft for internal use only – do not distribute

Background

The Drug Medi-Cal Organized Delivery System (DMC-ODS) 1115 demonstration waiver was created by the California Department of Health Care Services in 2015 to address gaps in patient access to and success in substance use disorder (SUD) treatment as a result of fragmented service system. Los Angeles County (LAC) joined as demonstration site in 2017.

Historically Ryan White (RW) SUD Services included Outpatient and Residential with three subcategories: Detox, Rehabilitation and Transitional. Under DMC-ODS, these services are provided by the LAC Substance Abuse Prevention and Control (SAPC) program that include:

- Outpatient (OP), Intensive outpatient (IOP)
- Opioid (narcotic) treatment program (OTP)
- Withdrawal management (WM)
- Medication-assisted treatment (MAT)
- Short- term residential (RS)
- Case management and care coordination with physical and mental health
- Recovery support services.

The current Ryan White SUD Services consists of one subcategory, residential housing, that was implemented March 1, 2019 (Ryan White Year 29) and intended to supplement DMC-ODS as Ryan White is the payer of last resort.

Overview of SUD Services

The current contracts for this service category are for RW years 29-31 (March 1, 2019-February 28, 2022). The contracted agencies include Tarzana Treatment Centers and Safe Refuge. The following details are summarized from the from the contract scope of work.

Contractor requirements

1. Licensed Programs: must operate as an adult residential facility, a community care facility, a transitional housing facility or a congregate living facility
2. Unlicensed programs: same facilities as listed for licensed with a current, written plan of operation on file.

Service Description: to provide interim housing with supportive services for up to one (1) year exclusively designated and targeted for recently homeless persons living with HIV/AIDS in various stages of recovery from substance use disorder. The purpose of the service is to facilitate continued recovery from substance abuse and movement toward more traditional,

permanent housing through assessment of the individual's needs, counseling, and case management.

Service Population: indigent persons living with diagnosed HIV in Los Angeles County who are:

1. Are homeless/unstably housed:
   a) Lack a fixed, regular, and adequate residence, as well as the financial resources to acquire shelter;
   b) Reside in a shelter designed to provide temporary, emergency living accommodations;
   c) Reside in an institution that provides a temporary residence for individuals intended to be institutionalized; or,
   d) Reside in a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings.
2. Uninsured or underinsured (current health plan does not cover services);
3. Have an income at or below 500% Federal Poverty Level; and,
4. In recovery.

Key Service Activities

1. Initial Intake: required during the first contact for all potential clients and includes
   a) Service eligibility and documentation
      - Proof of HIV diagnosis
      - Financial screening
      - Proof of residency in Los Angeles County
      - Proof of medical insurance or that client is underinsured or uninsured
      - Completion of a substance use treatment program in the past six weeks
      - In need of interim housing
   b) Client demographic data, emergency contact information, and next of kin, and
   c) Medical history complete with CD4 count and viral load measurements.
2. Assessment (agency-specific, not developed by DHSP)
3. Reassessment every 6 months (agency-specific, not developed by DHSP)
4. Client education (HIV/STD prevention and risk reduction, addiction education, medical complications of substance use, medication adherence)
5. Contagious/Infectious Disease Prevention and Intervention (screening and treatment for non-HIV infectious disease included Tuberculosis.
6. Treatment Plan (developed from assessment and updated at re-assessment every six months)
7. Referral Services (primary medical services, mental health, legal and financial services)
8. Partner Services (provided by contracted agency staff)
9. Support Services and Discharge Planning (includes written aftercare plan and specific SUD treatment recommendations).

Commented [WG1]: Would add Hepatitis

Limits on service utilization: shall not exceed one year per client with two six-month extensions (as approved by DHSP)

Bed hold policy: Contractor can hold a client's bed for up to two one-night bed holds per client per quarter for medical emergencies or therapeutic reasons. Unused bed holds cannot be carried forward

Reimbursement Structure

SUD Services – Residential has a fee-for-service reimbursement structure. This means contracted agencies are only reimbursed for those services they bill to DHSP.

Billable service units: number of days an individual occupied a bed (physically present in the facility overnight). This includes either the first day of admission or the day of discharge but not both unless entry and exit days are the same.

Service unit definition: day unit of services defined as a 24-hour period in which a resident receives housing and meals.

Service tracking measures:

1. Number of unduplicated clients
2. Number of service days delivered

Budget Information?

SUD services are supported through Ryan White Part B funds. Amount allocated for service by agency yrs. 29-30

Amount expended by agency

Contractor Reporting Requirements

1. Narrative Reports
   - Monthly reports (written report)
   - Semi-annual reports (six-month summary submitted January-June and July-December)
   - Annual report (written report for calendar year)
2. Client-level Data (submitted monthly through HIV Casewatch)
   - Eligibility data
   - Demographic/resource data
   - Service utilization data
     - Case Management Services (Tarzana only)

- HIV/STD Education (Tarzana only)
- Mental Health Services (Tarzana only)
- Routine Medical Care (Tarzana only)
- Vocational/Employment Counseling (Tarzana only)
- Transitional Housing (per day – Safe Refuge only)

- Core medical and support services outcomes, and
- Service linkages/referrals to other service providers

Service Utilization Summary for Year 29-30

A total of 115 clients utilized SUD Transitional Housing Services in Year 29 (March 1, 2019-February 28, 2020). Key client characteristics are described below. As Year 30 data is still under review, client demographics are not yet available.

- Race/Ethnicity: The majority of clients identified as Black (42%), followed by Latinx (34%), White (23%) and 1% were Asian.

- Gender Identity: Most clients identified as cisgender men (92%) while 3% identified as cisgender women and 3% as transgender women.

- Sex at Birth: Nearly all clients were male sex at birth (97%).

- Age: Most clients were aged 30-49 (53%), followed by client age 50-59 (23%), age 18-29 (17%) and 60 and older (7%).

- Primary Language: Nearly all clients (97%) identified English as their primary language.

- County of Birth: Nine out of 10 clients reported being born in the US (90%).

- Income by Federal Poverty Level (FPL): Nearly all clients were living at or below FPL (97%).

- Insurance Status: One in 8 clients was publicly insured (81%), 15% had no insurance and 4% had private or other insurance.

- Housing Status: Over half of clients reported experiencing homelessness at entry into services (51%), 26% were permanently housed, 21% were living in an institutional setting and 2% did not report.

- Incarceration History: Most clients had previous experience with the criminal justice system (57%).

- Receipt of Ryan White Medical Care: Few clients (6%) received medical care paid for by Ryan White in the reporting year.
- Engagement in HIV Care: Nearly all clients (99%) were engaged in HIV care during the reporting year.

- Retention in HIV Care: Most clients (84%) were retained in HIV care in the reporting year.

- Viral Suppression: Eight-seven percent (87%) of clients had suppressed HIV viral loads (less than 200 copies/mL at most recent test in the reporting period).

Listed below in Table 1 are the total number of clients for whom services were reported and paid for by DHSP in each Ryan White year, the total days of services provided and the average days of service per client. Note that no clients were reported by Safe Refuse in Year 30.

While the number of clients reported, the days of service reported and the averaged days of service per client increased from Year 29 to Year 30, please note that Year 30 data are preliminary but suggest that that Tarzana continued to provide these services during the COVID-19 stay at home orders.

Table 1: Total SUD Transitional Housing Clients Served by Contracted Agency, Los Angeles County, Ryan White Years 29-30* (March 1, 2019-February 28, 2021)

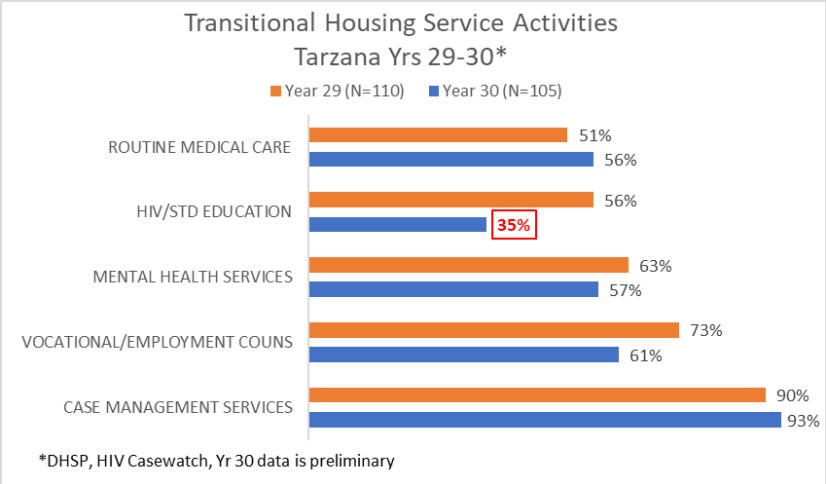
AGENCY	RW YEAR	TOTAL CLIENTS	DAYS OF SERVICE	AVERAGE DAYS PER CLIENT
SAFE REFUGE				
	29	5	653	130.6
	30	0	0	0
TARZANA				
	29	110	11,484	104.4
	30	105	11,872	113.1

*DHSP, HIV Casewatch, Year 30 data are preliminary

In addition to days of service, Tarzana also reported provision of specific service activities as presented below. Figure 1 presents the percent of clients who received each type of activity of the of the total number of clients served each year. Year 29 is represented by the orange bars and Year 30 by the blue bars. Further information is needed to understand if every client

should have received each service or whether this is determined by their care plan. Of note, there was a dramatic decrease in the proportion of clients who received HIV/STD education from Year 29 to Year 30.

Figure 1: Transitional Housing Service Activities Reported by Tarzana Treatment Centers, Years 29-30



Substance Abuse Services (Residential) per HRSA PCN #1602:

Description:
Substance Abuse Services (residential) is the provision of services for the treatment of drug or alcohol use disorders in a residential setting to include screening, assessment, diagnosis, and treatment of substance use disorder. This service includes:

- Pretreatment/recovery readiness programs
- Harm reduction
- Behavioral health counseling associated with substance use disorder
- Medication assisted therapy
- Neuro-psychiatric pharmaceuticals
- Relapse prevention
- Detoxification, if offered in a separate licensed residential setting (including a separately-licensed detoxification facility within the walls of an inpatient medical or psychiatric hospital)

Program Guidance:

Substance Abuse Services (residential) is permitted only when the client has received a written referral from the clinical provider as part of a substance use disorder treatment program funded under the RWHAP.

Substance Abuse Services (residential) are not allowable services under RWHAP Parts C and D.

Acupuncture therapy may be allowable funded under this service category only when it is included in a documented plan as part of a substance use disorder treatment program funded under the RWHAP.

RWHAP funds may not be used for inpatient detoxification in a hospital setting unless the detoxification facility has a separate license.

Drug Medi-Cal Organized Delivery System Waiver (DMC-ODS)

Frequently Asked Questions about the waiver that would expand benefits to treat Substance Use Disorders (SUD)

Implementing this waiver will test new ways of delivering healthcare services to Medi-Cal eligible individuals with SUD. California Counties can choose to opt-in. This sheet describes the impact this waiver would have if implemented in Los Angeles County.

1. Is Los Angeles County opting-in to the DMC-ODS Waiver?

Counties that choose to opt-in must submit approved implementation plans to participate in the DMC-ODS. Plans must be approved by their Boards of Supervisors, the California Department of Health Care Services, and the federal Centers for Medicaid and Medicare Services. The Substance Abuse Prevention and Control (SAPC) program within the Los Angeles County Department of Public Health intends to submit its implementation plan in January 2016. Once approved, counties will have three years to fully implement required DMC-ODS services.

2. How would the DMC-ODS Waiver change current SUD treatment services?

The DMC-ODS waiver would expand reimbursable services under the Drug Medi-Cal (DMC) program. Right now, the DMC only funds outpatient, intensive outpatient, and opioid (narcotic) treatment programs. Once implemented, this waiver would allow the use of DMC funds to support a more comprehensive continuum of care based on the American Society of Addiction Medicine (ASAM) Criteria. The table below lists the patient services that will be available based on determination of medical necessity and level of care (LOC) according to the ASAM criteria.

Benefits available to SUD Clients through the DMC-ODS Waiver

ASAM Service	Youth	Adults
Outpatient	☑	☑
Intensive Outpatient	☑	☑
Short-Term Residential	☑	☑
Withdrawal Management	N/A	☑
Opioid Treatment Programs	N/A	☑
Case Management	☑	☑
Recovery Support	☑	☑
Physician Consultations	☑	☑

Los Angeles County Department of Public Health
Substance Abuse Prevention and Control (SAPC)
http://publichealth.lacounty.gov/sapc/HeathCare/HealthCareReform.htm

County of Los Angeles Public Health

Revised 05/10/16

3. Who would be eligible for DMC-ODS Waiver services?

All Medi-Cal beneficiaries who live in counties that opt-in will be able to get new services available under the waiver. This includes previously eligible Medi-Cal beneficiaries (such as children in households with income up to 250% of the Federal Poverty Level) and the Medi-Cal expansion population (single adults without children with incomes up to 138% of the Federal Poverty Level). The services must be determined as medically necessary by a qualified physician.

4. What system-level changes would be required to implement the DMC-ODS Waiver?

Effective waiver implementation would require making various changes to the current service delivery system. Examples of such system-level changes include Los Angeles County, SAPC, and SAPC providers having to:

- Expand the SAPC SUD service provider network.
- Adopt standards of practice for the new systems of care.
- Develop workforce clinical skills in the use of evidence-based practices.
- Establish system-wide care coordination and linkages with physical health, mental health, and community support service systems.
- Establish a system-wide quality assurance and utilization management program.
- Establish a system-wide managed care information system and billing system.
- Develop a sustainable and financially-viable financing structure.

5. What would be the benefits and challenges of implementing the DMC-ODS Waiver?

Opting-in to implement this waiver requires considering the benefits and challenges that may arise:

Benefits	Challenges
• Extends eligibility for DMC benefits and delivers care to many more people (e.g. adults without children, people experiencing homelessness or reentering communities from incarceration) with the aim of improving access to services, health outcomes, and quality of life.	• Requires all DMC waiver services to be delivered by a DMC-certified provider. SAPC will be able to provide technical assistance to help providers complete the DMC and ASAM certification processes to expand the SAPC network of treatment providers and the SUD services workforce to ensure access to all LOCs.
• Creates an organized system of care that connects providers that offer a broad range of services, and allows them to deliver and receive payment for medically necessary services that they provide in the community, outside of clinical facilities.	• Requires enhancing quality assurance and utilization management capacity to ensure optimal care for clients and smooth transitions across different types and levels of care.
• Ensures services are evidence-based and provided at the right LOC that meets client needs based on medical necessity.	• Requires integrated service delivery networks to treat the whole person, using system-wide planning efforts and case management to coordinate the SUD service delivery system with the physical and mental health systems, as well as with criminal justice, homeless, and juvenile justice/dependency/foster care service providers/partners.
• Prevents the use of high-cost health services (e.g. emergency department visits and hospitalizations) leading to cost savings across the health care delivery system.	
• Moves SAPC toward a specialty health plan model.	
• Treats SUD as a chronic disease, building quality improvement processes and broader service integration with physical health, mental health, and social service providers.	

STANDARDS OF CARE FOR HIV SUBSTANCE USE RESIDENTIAL AND TREATMENT SERVICES

Suggestions:
Change "measure" to "documentation"
Add hyperlinks to SAPC AOD certification standards
Add hyperlinks to SAPC Level of Care and Residential Designation links
Add hyperlinks to the CA Department of Healthcare Services

Approved by the Commission on HIV on 4/13/2017

TABLE OF CONTENTS

SUBSTANCE USE SERVICES STANDARDS OF CARE

Substance Use Outpatient/Treatment Services Definition
Per HRSA Policy Guidance, Substance Use Outpatient Care is the provision of outpatient services for the treatment of drug or alcohol use disorders. Services include:

- Screening
- Assessment
- Diagnosis, and/or Treatment of substance use disorder, including:
    - Pretreatment/recovery readiness programs
    - Harm reduction
    - Behavioral health counseling associated with substance use disorder
    - Outpatient drug-free treatment and counseling
    - Medication assisted therapy
    - Neuro-psychiatric pharmaceuticals
    - Relapse prevention

Substance Use Residential Services
Per HRSA Policy Guidance, Substance Use Services (residential) is the provision of services for the treatment of drug or alcohol use disorders in a residential setting to include screening, assessment, diagnosis, and treatment of substance use disorder. This service includes:

- Pretreatment/recovery readiness programs
- Harm reduction
- Behavioral health counseling associated with substance use disorder
- Medication assisted therapy
- Neuro-psychiatric pharmaceuticals
- Relapse prevention

Detoxification, if offered in a separate licensed residential setting (including a separately-licensed detoxification facility within the walls of an inpatient medical or psychiatric hospital)

Program Guidance:
Substance Use Services (residential) is permitted only when the client has received a written referral from the clinical provider as part of a substance use disorder treatment program funded under the RWHAP.

Substance Use Services Standards of Care
The overall objectives of the Substance Use Services standards of care are to:

- comply with state regulations, including licensing requirements, for substance Use services; and
- provide services with skilled, licensed professionals with experience and/or education in relevant disciplines.

The service specific standards of care for Substance Use Services provide additional

requirements around the following components of service provision:

A. Agency Licensing and Policies
B. Competencies

Substance Use Services providers are expected to comply with the Universal Standards of Care, as well as these additional standards.

A. Agency Licensing and Policies

The objective of the standards for agency licensing and policies for Substance Use Services is to ensure that programs comply with state regulations and licensing requirements.

If residential substance Use treatment services are provided in a facility that primarily provides inpatient medical or psychiatric care, the component providing the substance Use treatment must be separately licensed for that purpose.

A. Agency Licensing and Policies (Substance Use)	
Standard	**Measure**
Agency is licensed and accredited by appropriate state and local agency to provide substance Use services.	Current license(s) on file.

B. Competencies

The objective of the competencies standards for Substance Use Services is to ensure that clients have access to the highest quality services through experienced and trained staff.

B. Competencies (Substance Use)	
Standard	**Measure**
Staff members are licensed or certified, as necessary, to provide substance Use services and have experience and skills appropriate to the specified substance Use treatment modality.	Current license and résumé on file.

Key systems level changes affecting substance use disorder (SUD) treatment in Los Angeles County:

The Drug Medi-Cal Organized Delivery System (DMC-ODS) is a new health care services paradigm for Medi-Cal eligible individuals with substance use disorders (SUD). The Los Angeles County Department of Public Health, Substance Use Prevention and Control (SAPC) will implement an initial benefit package for SUD services within the initial 12 months of approval

from the California Department of Health Care Services (DHCS). California's Medi-Cal 2020 1115(a) Waiver Demonstration Project paves the way for Los Angeles County (LAC) to increase access to substance use disorder (SUD) treatment services for adolescents and adults who are eligible for Medi-Cal.

It expands Drug Medi-Cal (DMC) reimbursable services beyond outpatient (OP), intensive outpatient (IOP), and opioid (narcotic) treatment program (OTP) to create a fuller continuum of care that includes withdrawal management (WM), medication-assisted treatment (MAT), short-term residential (RS), case management and care coordination with physical and mental health, and recovery support services. With the new benefits, also comes the responsibility to make placement decisions based on the American Society of Addiction Medicine (ASAM) Criteria and medical necessity; provide care at the lowest and most appropriate level of care (LOC), including improved transitions between LOCs; and use MAT in conjunction with other treatment services.

UPDATES TO SUBSTANCE USE SERVICES STANDARDS OF CARE:

As Ryan White serves as the payor of last resort for critical HIV/AIDS care and treatment services, its service level standards must align with SAPC's standards. In recognition of these systems-level changes to the treatment of SUD in publicly funded settings, the following changes are noted in the Substance Use Treatment and Residential Standards of Care:

- All Ryan White funded substance Use services must provide integrated services of behavioral health treatment and HIV medical care. An integrated behavioral health and HIV medical care program addresses alcohol, marijuana, cocaine, heroin, injection drug use (IDU), and prescription drug misuse; mental disorder treatment and HIV/viral hepatitis services, including HIV and hepatitis B and C testing; and use evidence-based interventions defined by the Substance Use and Mental Health Services Administration (SAMHSA).

- Use a trauma-informed approach following SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach (http://store.samhsa.gov/product/SAMHSA-s-Concept-of-Trauma-and-Guidance-for-aTrauma-Informed-Approach/SMA14-4884).

- Link clients and partners to appropriate community-based behavioral health services/systems including primary HIV care and antiretroviral treatment (ART), HIV pre-exposure prophylaxis (PrEP), primary health care, and other recovery support services.

- Offer and use appropriate behavioral health services include engagement services (e.g., outreach, assessment, service planning); outpatient treatment services; intensive outpatient treatment services; substance use or mental disorders residential treatment services; medication-assisted treatment (MAT); community support services such as case management (e.g., assessment, planning, linking, monitoring, and advocacy), and peer and other recovery support services http://www.samhsa.gov/recovery.

- Use the Medical Care Coordination Assessment tool to determine acuity level and eligibility for MCC services.

- Screen and assess clients for the presence of co-occurring mental disorders and use the information obtained from the screening and assessment to develop appropriate treatment approaches for the persons identified as having co-occurring disorders.

- Ensure that patients who need trauma-related services have access to these services through case management and referral to certified trauma providers.

- All clients who are considered to be at risk for vital hepatitis (B and C), as specified by the United States Preventive Services Task Force (USPSTF) recommendations for hepatitis B and hepatitis C screening, must be tested for viral hepatitis (B and C) in accordance with state and local requirements, either onsite or through referral.

- Provide a plan for providing referrals and linkages to follow-up care and treatment for all individuals infected with viral hepatitis (B or C).

- Develop a plan for case management of all clients who have a preliminary positive HIV and confirmatory HIV test result. The process of case management includes: comprehensive assessment of the client's needs and development of an individualized service plan.

- Medication Assisted Treatment (MAT) is an evidence-based substance Use treatment therapy. SAMHSA supports the right of individuals with an opioid or alcohol use disorder to be given access to MAT as appropriate under the care of a physician.

- Screen and assess clients for the presence of co-occurring mental and substance use disorders and use the information obtained from the screening and assessment to develop appropriate treatment approaches for the persons identified as having such co-occurring disorders.

Substance Use Treatment	
Standard	**Measure**
Providers must provide the following service components: • Intake • Individual counseling • Group counseling • Patient education • Family therapy • Medication services • Collateral services • Crisis intervention services • Treatment planning • Discharge services	A comprehensive written program service delivery protocol outlining how staff will deliver all service components based on SAPC, SAMHSA and ASAM guidelines.
Providers are responsible to provide culturally competent services. Services must be embedded in the organizational structure and upheld in day-to-day operations.	Agencies must have in place policies, procedures and practices that are consistent with the principles outlined in the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS).
Agencies provide services that accounts for a client's age and developmental level to ensure his/her engagement into the treatment process.	Use of assessment and screening tools that establishes age and developmental levels and appropriate individualized treatment plan. Case notes clearly articulate action steps and treatment modifications for the client's age and developmental level.
Agencies must have procedures for linkage/integration of Medication-Assisted Treatment (MAT) for patients to ensure adequate access to core components of substance use disorder (SUD) treatment.	Established protocols for MAT following prescribing standards from the American Society of Addiction Medicine (ASAM) and SAMHSA.
Agencies must use Evidence-Based Practices such as Motivational Interviewing and Cognitive Behavioral Therapy, relapse prevention, trauma-informed treatment, and psychoeducation.	Written evidence-based program protocol.
Agencies must provide Field-Based Services (FBS) based on comprehensive assessment.	Proper certifications are in place for staff to provide FBS. Written FBS protocol.
Providers must deliver a variety of case management and care coordination services	Written case management and care coordination protocol.

including transitioning clients from one level of care to another and navigating the mental health, physical health, and social service delivery systems.	MOUs with agencies for ensuring coordination of services for patients. List of service providers and partners.
Providers must delivery recovery support services to clients upon discharge from treatment services, including outpatient /intensive outpatient programs.	Written recovery support services protocol. MOUs with agencies for ensuring coordination of care.
Agencies must maintain complete and thorough documentation of services provided to client.	Agencies maintain documentation based on the ASAM Criteria. Progress notes are thorough, dated, and verified by a licensed supervisor.

Substance Use – Residential	
Standard	**Measure**
Providers must provide the following service components: • Intake • Individual counseling • Group counseling • Patient education • Family therapy • Safeguard medications • Medication services • Collateral services • Crisis intervention services • Treatment planning • Transportation services • Discharge services	A comprehensive written program service delivery protocol outlining how staff will deliver all service components based on SAPC, SAMHSA and ASAM guidelines.
Appropriate medical evaluation must be performed prior to initiating residential treatment services, including physical examinations when deemed necessary.	Medical record of physical examinations and medical evaluation by a licensed medical provider.
Providers are responsible to provide culturally competent services. Services must be embedded in the organizational structure and upheld in day-to-day operations.	Agencies must have in place policies, procedures and practices that are consistent with the principles outlined in the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS).
Agencies must have procedures for linkage/integration of Medication-Assisted Treatment (MAT) for patients to ensure adequate access to core components of	Established protocols for MAT following prescribing standards from the American Society of Addiction Medicine (ASAM) and SAMHSA.

substance use disorder (SUD) treatment.	
Agencies must use Evidence-Based Practices such as Motivational Interviewing and Cognitive Behavioral Therapy, relapse prevention, trauma-informed treatment, and psychoeducation.	Written evidence-based program protocol.
Case management will assist patients in navigating and accessing mental health, physical health, and social service delivery systems.	Case notes must show that the initiating provider provided case management services and communicated with the next provider along the continuum of care to ensure smooth transitions between levels of care. If the client is referred to a different agency, case notes must show that the client has been successfully admitted for services with the new treating provider.
Providers must delivery recovery support services to clients to sustain engagement and long-term retention in recovery, and re-engagement in SUB treatment and other services and supports as needed.	Written recovery support services protocol. MOUs with agencies for ensuring coordination of care.
Agencies must maintain complete and thorough documentation of services provided to client.	Agencies maintain documentation based on the ASAM Criteria.

ACKNOWLEDGMENTS

This document was under the guidance of the Los Angeles County Commission on HIV, Standards and Best Practices (SBP) Committee and critique from subject matter experts. We thank them for their leadership and dedication to ensuring that high quality HIV services are accessible to PLWHA.

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LOS ANGELES COMMISSION ON HIV
PERCENTAGE ALLOCATIONS FOR RYAN WHITE PROGRAM YEARS 30, 31, 32
Approved 9/10/2020

	RW Service Allocation Descriptions	FY 2020 PY 30		FY 2021 PY 31		FY 2022 (PY 32)
PY 30 Priority #	Service Category	Part A %	MAI %	Part A %	MAI %	Total Part A/MAI %
1	Outpatient/Ambulatory Health Services (AOM)	27.24%	0.00%	27.21%	0.00%	28.30%
NP	AIDS Drug Assistance Program (ADAP) Treatments	0.0%	0.00%	0.00%	0.00%	0.00%
26	AIDS Pharmaceutical Assistance (local)	0.00%	0.00%	0.00%	0.00%	0.00%
11	Oral Health	14.10%	0.00%	13.04%	0.00%	12.00%
7	Early Intervention Services	0.59%	0.00%	0.59%	0.00%	1.25%
20	Health Insurance Premium & Cost Sharing Assistance	0.00%	0.00%	0.00%	0.00%	0.00%
17	Home Health Care	0.00%	0.00%	0.00%	0.00%	0.00%
16	Home and Community Based Health Services	6.67%	0.00%	6.70%	0.00%	5.91%
27	Hospice Services	0.00%	0.00%	0.00%	0.00%	0.00%
3	Mental Health Services	0.60%	0.00%	0.60%	0.00%	0.00%
23	Medical Nutritional Therapy	0.00%	0.00%	0.0%	0.00%	0.05%
4	Medical Case Management (MCC)	29.88%	0.00%	29.83%	0.00%	25.60%
18	Substance Abuse Services Outpatient	0.00%	0.00%	0.0%	0.00%	0.00%
10	Case Management (Non-Medical) BSS/TCM	5.92%	6.14%	5.91%	10.53%	8.60%
14	Child Care Services	0.00%	0.00%	1.00%	0.00%	1.00%
8	Emergency Financial Assistance		0.00%	0.00%	0.00%	2.50%
13	Food Bank/Home-delivered Meals	5.95%	0.00%	5.94%	0.00%	5.27%
6	Health Education/Risk Reduction	0.00%	0.00%	0.00%	0.00%	0.00%
2	Housing Services RCFCI/TRCF/Rental Subsidies with CM	1.42%	93.86%	1.56%	89.47%	5.00%
21	Legal Services	0.16%	0.00%	0.16%	0.00%	1.00%
22	Linguistic Services	0.00%	0.00%	0.00%	0.00%	0.00%
9	Medical Transportation	1.89%	0.00%	1.89%	0.00%	1.52%
5	Outreach Services (LRP)	5.57%	0.00%	5.56%	0.00%	0.00%
12	Psychosocial Support Services	0.00%	0.00%	0.00%	0.00%	2.00%
19	Referral	0.00%	0.00%	0.00%	0.00%	0.00%
24	Rehabilitation	0.00%	0.00%	0.00%	0.00%	0.00%
25	Respite Care	0.00%	0.00%	0.00%	0.00%	0.00%
15	Substance Abuse Residential	0.00%	0.00%	0.00%	0.00%	0.00%
	Overall Total	**100.0%**	**100.00%**	**100.0%**	**100.0%**	**100.00%**

ORIGINAL ARTICLE

Bupropion and Naltrexone in Methamphetamine Use Disorder

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ABSTRACT

BACKGROUND

The use of naltrexone plus bupropion to treat methamphetamine use disorder has not been well studied.

METHODS

We conducted this multisite, double-blind, two-stage, placebo-controlled trial with the use of a sequential parallel comparison design to evaluate the efficacy and safety of extended-release injectable naltrexone (380 mg every 3 weeks) plus oral extended-release bupropion (450 mg per day) in adults with moderate or severe methamphetamine use disorder. In the first stage of the trial, participants were randomly assigned in a 0.26:0.74 ratio to receive naltrexone–bupropion or matching injectable and oral placebo for 6 weeks. Those in the placebo group who did not have a response in stage 1 underwent rerandomization in stage 2 and were assigned in a 1:1 ratio to receive naltrexone–bupropion or placebo for an additional 6 weeks. Urine samples were obtained from participants twice weekly. The primary outcome was a response, defined as at least three methamphetamine-negative urine samples out of four samples obtained at the end of stage 1 or stage 2, and the weighted average of the responses in the two stages is reported. The treatment effect was defined as the between-group difference in the overall weighted responses.

RESULTS

A total of 403 participants were enrolled in stage 1, and 225 in stage 2. In the first stage, 18 of 109 participants (16.5%) in the naltrexone–bupropion group and 10 of 294 (3.4%) in the placebo group had a response. In the second stage, 13 of 114 (11.4%) in the naltrexone–bupropion group and 2 of 111 (1.8%) in the placebo group had a response. The weighted average response across the two stages was 13.6% with naltrexone–bupropion and 2.5% with placebo, for an overall treatment effect of 11.1 percentage points (Wald z-test statistic, 4.53; P<0.001). Adverse events with naltrexone–bupropion included gastrointestinal disorders, tremor, malaise, hyperhidrosis, and anorexia. Serious adverse events occurred in 8 of 223 participants (3.6%) who received naltrexone–bupropion during the trial.

CONCLUSIONS

Among adults with methamphetamine use disorder, the response over a period of 12 weeks among participants who received extended-release injectable naltrexone plus oral extended-release bupropion was low but was higher than that among participants who received placebo. (Funded by the National Institute on Drug Abuse and others; ADAPT-2 ClinicalTrials.gov number, NCT03078075.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Trivedi at the University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390-9119, or at madhukar.trivedi@utsouthwestern.edu.

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There has been a rise in methamphetamine use disorder in the United States, particularly in the Midwest and West, where methamphetamine is a leading cause of overdose deaths.[1,2] There is no medication approved by the Food and Drug Administration for the treatment of methamphetamine use disorder, and effective treatment has been identified as an essential public health goal.[3,4]

Bupropion[5-7] and naltrexone[8-10] used individually have shown some positive evidence of efficacy in clinical trials for the treatment of methamphetamine use disorder.[11-13] Bupropion is a stimulant-like antidepressant that acts through the norepinephrine and dopamine systems and might ameliorate the dysphoria associated with methamphetamine withdrawal that drives continued use.[14,15] Naltrexone is an opioid-receptor antagonist that is effective for the treatment of opioid use disorder. In some trials, it has also been shown to have a modest effect in preventing relapse of alcohol use,[16] perhaps by attenuating the reinforcing effects of substances or cue-induced cravings.[10,17,18] The results of a small, open-label pilot trial suggested that naltrexone plus bupropion might be effective for the treatment of severe methamphetamine use disorder.[19] These findings supported the development of the current trial (Accelerated Development of Additive Treatment for Methamphetamine Disorder [ADAPT-2]), which assessed the efficacy of combining these agents for the treatment of methamphetamine use disorder.

METHODS

TRIAL DESIGN AND CONDUCT

This randomized, double-blind trial, which used a sequential parallel comparison design,[20,21] was conducted at eight sites from May 23, 2017, to July 25, 2019. It evaluated the efficacy and safety of extended-release injectable naltrexone (380 mg every 3 weeks) combined with once-daily oral extended-release bupropion (450 mg per day) as compared with placebo in adult outpatients with moderate or severe methamphetamine use disorder.

This 12-week trial was conducted in two stages consisting of 6 weeks each. Participants initially underwent randomization in a 0.26:0.74 ratio to receive naltrexone–bupropion or placebo during the first 6-week stage; participants in the placebo group who did not have a response in the first stage underwent randomization again in a 1:1 ratio in the second 6-week stage (Fig. 1). The ratios used for randomization were chosen on the basis of established practices in sequential parallel design trials and are described in the Statistical Analysis section and in the statistical analysis plan, included in the protocol (available with the full text of this article at NEJM.org).[22] The purpose of rerandomization was to enrich the sample in the second stage with participants who were unlikely to have a response to placebo. The results from both stages were combined for analysis as described in the statistical analysis plan.

Participants visited the clinic twice a week for drug screening of urine samples (for a potential total of 24 urine samples per participant [12 in each stage]), for safety monitoring, and for assessments. Additional safety and outcome assessments were performed at week 6 and week 12. The integrity of urine samples was determined with the use of an embedded temperature strip on the collection cup (valid samples were considered to be those with a temperature of 32° to 38°C [90° to 100°F]) and a negative test for adulterants. Valid samples were tested for 10 drugs with the use of a point-of-care urine drug test card in accordance with the regulations of the Clinical Laboratory Improvement Amendments of 1988.

Extended-release naltrexone was supplied in standard single-use intramuscular injection kits, each containing one 380-mg vial of naltrexone microspheres. In each stage, injections of naltrexone or placebo were administered by trial clinicians on the day of randomization (or rerandomization) and in the third week of each stage. Naltrexone was administered every 3 weeks to mitigate the lower naltrexone blood levels that would most likely occur with a 4-week injection schedule, according to the product labeling.

Extended-release bupropion (in 150-mg tablets) or placebo was provided weekly in matching blister cards. Beginning on the day of randomization or rerandomization, the dose was raised over the course of 3 days to a total daily dose of 450 mg. If appropriate, doses could be reduced before week 13 to 300 mg per day to alleviate adverse effects; clinicians were encouraged to attempt to raise the dose back up to the target dose. At the end of the trial (week 13), the dose was tapered over a period of 4 days, at which point it was discontinued.

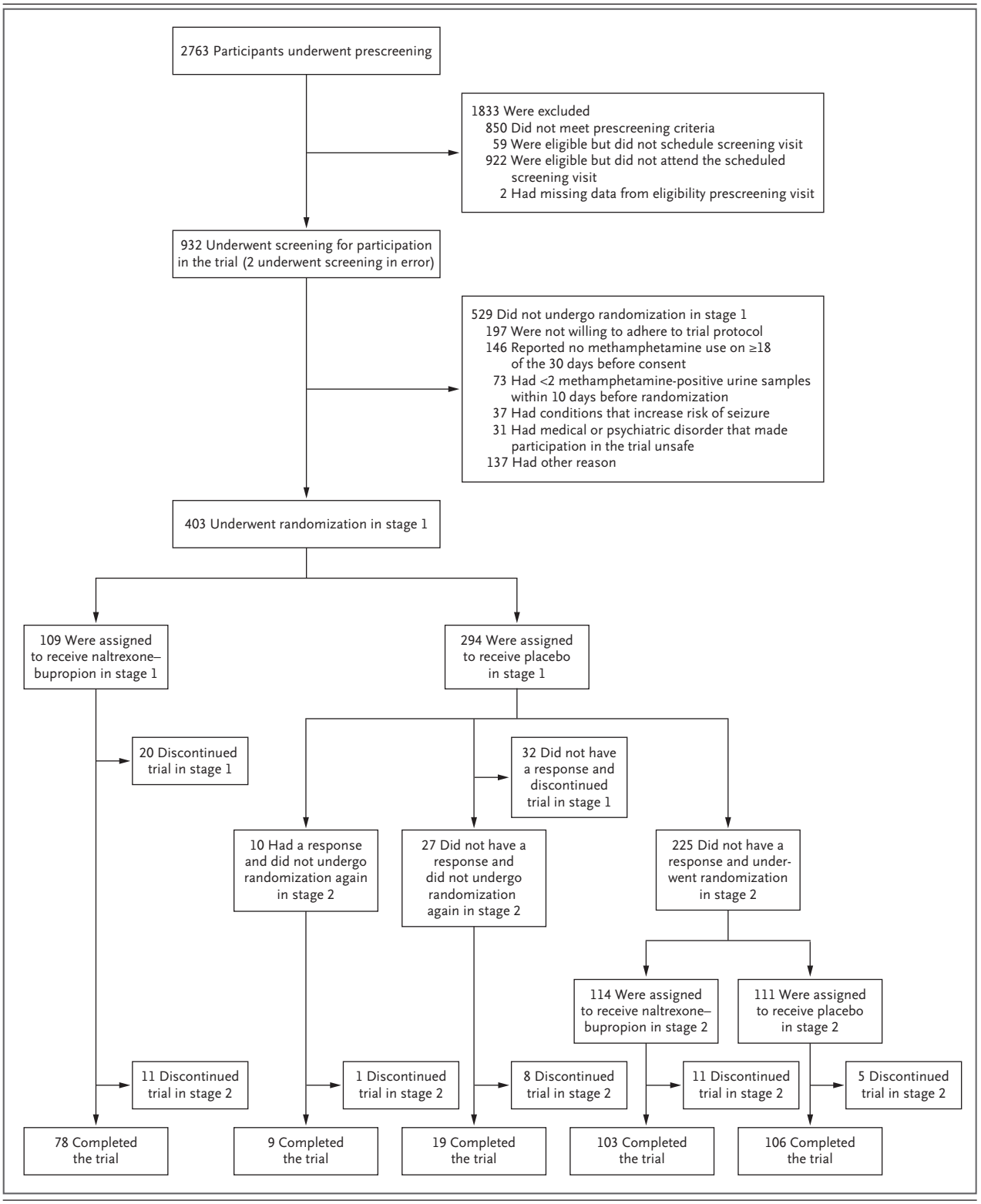


Figure 1 (facing page). Screening and Randomization.
Participants may have had more than one reason for not undergoing randomization in stage 1. The analysis of the primary outcome was performed in the intention-to-treat population, which included all participants who underwent randomization in stage 1 and all participants who underwent randomization again in stage 2.

Adherence to the assigned regimen was determined by participant-reported tablet ingestion (confirmed on the basis of tablet count) and by documentation by the trial staff who administered the injections. To encourage adherence, participants were asked to use a smartphone-based application to track tablet ingestion. Trial clinicians, who were unaware of group assignments, met weekly with participants to manage adverse events, assess and encourage adherence to the oral regimen, address participant concerns, and provide counseling for reducing substance use.

TRIAL OVERSIGHT

The trial was conducted in accordance with the principles of the Declaration of Helsinki. The protocol was approved by the data and safety monitoring board of the National Institute on Drug Abuse (NIDA) Clinical Trials Network, by a central institutional review board, and by institutional review boards at four sites. The data and safety monitoring board monitored trial progress and safety, reviewed a one-time sample-size re-estimation and interim efficacy analysis, and appraised the final outcome and safety results. The data analysis was performed by the fifth, sixth, and eighth authors. The first draft of the manuscript was written by the second author. All authors vouch for the adherence of the trial to the protocol, the completeness and accuracy of the data, and the complete reporting of adverse events. Alkermes donated naltrexone in the form of extended-release injectable suspension and matched injectable placebo for this trial under a written agreement with NIDA (the sponsor). AiCure (New York) provided the smartphone-based application for tracking adherence to the oral regimen under a paid subcontract. Neither company had a role in the collection or analysis of the data or the writing of the manuscript. There were no confidentiality agreements between the investigators and the commercial entities.

PARTICIPANTS

Adults 18 to 65 years of age who wanted to quit or reduce methamphetamine use were recruited from communities near the trial sites with the use of advertisements (e.g., print, Web, radio, and television advertising) and through direct referrals (e.g., by participants who were already enrolled in the trial, medical clinics, and social-service agencies). Eligible participants met the criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition (DSM-5), for moderate or severe stimulant use disorder (methamphetamine type); reported methamphetamine use on at least 18 of the 30 days before consent; had two or more methamphetamine-positive urine samples (obtained ≥2 days apart) within 10 days before randomization; and were opioid-free at the time of randomization. Participants were excluded if they were undergoing concurrent treatment for substance use disorder, had an expected need for opioid-containing medications (e.g., planned surgery) during the trial, or did not meet additional criteria that would ensure that participation would be safe (e.g., participants would not be eligible if they had conditions that increased the risk of seizure or were taking medications that were contraindicated). Participants who had received a diagnosis of a specific medical or psychiatric disorder were not routinely excluded and were evaluated on a case-by-case basis to determine whether it was safe for them to participate.

Persons who were interested in participation completed a brief telephone prescreening, and, if appropriate, a visit was scheduled so that participants could learn about trial procedures and the potential benefits and risks of participation, have the opportunity to ask questions, and provide written informed consent. After consent was obtained, a screening period of 4 to 21 days was begun to evaluate eligibility criteria. Eligible participants were then randomly assigned to receive naltrexone–bupropion or placebo. Participants were compensated for participation in the trial. Details on eligibility criteria and compensation are provided in the protocol.

OUTCOMES

The primary outcome was a response to the trial regimen, defined as at least three methamphetamine-negative urine tests out of a possible four obtained at the end of stage 1 (during week 5 through week 6) or at the end of stage 2 (during week 11 through week 12). A response was included in the analysis only in the stage in which it first occurred. Participants who had two or more missing results of urine drug screenings or who discontinued the trial were recorded as not having had a response. To combine results across the two trial stages, the weighted average of the responses across the two stages was calculated for each trial group. The overall treatment effect was defined as the between-group difference in the weighted responses.

Secondary outcomes that were evaluated in each stage were the percentage of methamphetamine-negative urine samples (i.e., the number of methamphetamine-negative urine samples per stage divided by 12, which was the total number of samples expected in each stage); the most severe methamphetamine craving during the previous week,[23] assessed weekly with the use of a visual analogue scale (values range from 0 to 100, with higher values indicating greater cravings); depressive symptoms, assessed weekly with the use of the Patient Health Questionnaire 9 (PHQ-9; each of nine items is given a score of 0 to 3, with a score of 0 indicating the absence of depressive symptoms and a score of 3 indicating the presence of depressive symptoms nearly every day; total scores range from 0 to 27, with higher scores indicating greater depressive symptoms); and results of the Treatment Effectiveness Assessment at week 6 and week 12, which assesses reduced substance use and improvements in lifestyle, health, and community and interpersonal interactions according to participant report[24,25] (total scores range from 4 to 40, with higher scores indicating greater improvement in these factors).

Safety outcomes were assessed at each visit and included participant-reported adverse events and assessment of vital signs, liver-function tests, injection-site reactions, results on electrocardiograms, and suicidality.[26] Adverse events were classified according to the preferred term and system organ class of the *Medical Dictionary for Regulatory Activities*, version 22.1. Site investigators, who were unaware of trial-group assignments, determined whether an event was a serious adverse event and evaluated the severity and cause of the event. Serious adverse events were adjudicated by a medical monitor assigned by the sponsor.

STATISTICAL ANALYSIS

According to the sample-size calculation,[22] we determined that 370 participants would give the trial 90% power to detect a weighted difference between the two trial groups under the assumption that 24% of participants in the naltrexone–bupropion group and 15% in the placebo group would have a response in stage 1, and 24% in the naltrexone–bupropion group and 10% in the placebo group would have a response in stage 2. The assumption that 24% of participants in the naltrexone–bupropion group would have a response was determined on the basis of a small pilot study.[19] Because the goal of stage 2 was to enrich the sample by including only participants in the placebo group who did not have a response in stage 1, we expected a smaller number of participants in the placebo group to have a response in stage 2 than in stage 1. The prespecified sample-size reestimation analysis was performed with data from the first 185 participants who underwent randomization. Investigators were not informed of the results of the reestimation analysis. The data and safety monitoring board recommended increasing the sample size to 400 to maintain 90% power to detect a difference in response between the two groups. This recommendation was approved by the sponsor on August 13, 2018.

The trial used a two-stage, sequential parallel comparison design.[20,21] This design requires two parameters: a randomization fraction and a weight. Each value was chosen to maximize the power of the test in accordance with the sample-size calculation, resulting in a randomization ratio in stage 1 of 0.26:0.74 to naltrexone–bupropion or placebo. The overall treatment effect with this design was defined as the average response in the naltrexone–bupropion group minus the average response in the placebo group, calculated with the use of a weight of 0.43 in stage 1 and a weight of 0.57 in stage 2. Additional information regarding the formula used to calculate the size of the treatment effect, $h = [w(p1) + (1 - w)$

p2] − [w(q1) + (1 − w)(q2)] (with h indicating the overall treatment effect, w indicating the weight, p1 indicating the response in the naltrexone–bupropion group in stage 1, p2 indicating the response in the naltrexone–bupropion group in stage 2, q1 indicating the response in the placebo group in stage 1, and q2 indicating the response in the placebo group in stage 2), is provided in the statistical analysis plan.

The analyses were performed in the intention-to-treat population, which included all participants who underwent randomization in stage 1 and all participants who underwent randomization again in stage 2 (Fig. S1 in the Supplementary Appendix, available at NEJM.org). The primary outcome was evaluated with the use of a one-sided Wald z-test statistic[22] with a one-sided type I error rate of 0.025, corresponding to a two-sided test with an alpha level of 0.05. The standard error of h accounted for the inclusion of some participants from stage 1 in stage 2. To determine the sensitivity of these results, we repeated the primary outcome analysis with the use of a prespecified complete-case approach (a complete case was defined as four urine samples obtained during the final 2 weeks of each stage). We conducted an additional prespecified sensitivity analysis that assumed equal weight for each stage. Subgroup effects according to trial site, sex, race, ethnic group, and age were assessed with the use of generalized linear mixed models and a forest plot presenting the treatment effect with 95% confidence intervals.

Secondary outcomes were analyzed with the use of the Doros method[27] for repeated measures of a continuous outcome. Because there was no prespecified plan for adjustment of confidence intervals for multiple comparisons of secondary outcomes, no clinical conclusions can be drawn from these results. Adverse events were compared between groups in stage 1 and stage 2 with Fisher's exact tests. All analyses were conducted with SAS software, version 9.4 (SAS Institute).

RESULTS

PARTICIPANTS

A total of 403 participants underwent randomization in stage 1: 109 participants (27.0%) were assigned to receive naltrexone–bupropion, and 294 (73.0%) to receive placebo (Fig. 1). Of the 225 participants in the placebo group who did not have a response in stage 1 and underwent randomization again in stage 2, a total of 114 (50.7%) were assigned to receive naltrexone–bupropion and 111 (49.3%) to receive placebo. The 403 participants who underwent randomization in stage 1 were assessed for the primary outcome at the end of the trial. Table 1 shows demographic and clinical characteristics of all participants according to group assignment. The average age of participants was 41 years, 68.7% were male, 71.2% were White, and 38.7% were employed. On average, participants used methamphetamine on 27 of the 30 days before consent was provided.

In stage 1, adherence to the assigned regimen was 75.1% in the naltrexone–bupropion group (63.9% to the oral regimen and 86.2% to the injection) and 83.5% in the placebo group (74.1% and 92.7%, respectively). In stage 2, adherence was 77.4% in the naltrexone–bupropion group (68.8% to the oral regimen and 86.4% to the injection) and 82.0% in the placebo group (75.1% and 89.2%, respectively).

PRIMARY OUTCOME

The primary outcome was a response, defined as at least three methamphetamine-negative urine samples out of a possible four samples obtained at the end of stage 1 (during week 5 through week 6) or the end of stage 2 (during week 11 through week 12). At the end of stage 1, a total of 16.5% (18 of 109 participants) in the naltrexone–bupropion group and 3.4% (10 of 294 participants) in the placebo group had a response. At the end of stage 2, a total of 11.4% (13 of 114 participants) in the naltrexone–bupropion group and 1.8% (2 of 111 participants) in the placebo group had a response (Table 2). After weighting and combining the percentage of responses across the stages, we calculated that the overall weighted response was 13.6% in the naltrexone–bupropion group and 2.5% in the placebo group (Fig. 2A). The treatment effect, defined as the between-group difference in the overall weighted response, was 11.1 percentage points (lower boundary of the 95% confidence interval [CI], 6.3; Wald z-test statistic, 4.53; P<0.001) (Table 2 and Fig. 2A). Figure 2B shows methamphetamine-negative urine results across trial visits;

Table 1. Baseline Characteristics of the Participants in the Intention-to-Treat Population.*

Characteristic	All Participants	Stage 1		Stage 2	
	Total† (N=403)	Naltrexone–Bupropion (N=109)	Placebo (N=294)	Naltrexone–Bupropion (N=114)	Placebo (N=111)
Demographic characteristics					
Male — no. (%)	277 (68.7)	78 (71.6)	199 (67.7)	78 (68.4)	79 (71.2)
Age — yr	41.0±10.1	41.0±10.6	41.0±10.0	41.0±10.5	42.0±9.6
Hispanic or Latino ethnic group — no. (%)‡	55 (13.6)	13 (11.9)	42 (14.3)	20 (17.5)	18 (16.2)
Race or ethnic group — no. (%)‡					
White	287 (71.2)	82 (75.2)	205 (69.7)	84 (73.7)	69 (62.2)
Black	48 (11.9)	10 (9.2)	38 (12.9)	8 (7.0)	22 (19.8)
Other	68 (16.9)	17 (15.6)	51 (17.3)	22 (19.3)	20 (18.0)
High school diploma, GED, or lower education level — no. (%)	142 (35.2)	39 (35.8)	103 (35.0)	36 (31.6)	33 (29.7)
Marital status — no. (%)					
Married or living with partner	93 (23.1)	26 (23.9)	67 (22.8)	25 (21.9)	25 (22.5)
Never married	204 (50.6)	49 (45.0)	155 (52.7)	60 (52.6)	59 (53.2)
Divorced, separated, widowed, or unknown — no. (%)	106 (26.3)	34 (31.2)	72 (24.5)	29 (25.4)	27 (24.3)
Employed — no. (%)§	156 (38.7)	43 (39.4)	113 (38.4)	46 (40.4)	44 (39.6)
Methamphetamine use					
No. of days that methamphetamine was used in the 30 days before consent¶	26.7±4.1	27.0±3.9	26.5±4.2	26.7±4.1	26.1±4.3
Most frequent route of methamphetamine use — no. (%)					
Smoking	293 (72.7)	80 (73.4)	213 (72.4)	83 (72.8)	79 (71.2)
Intravenous	77 (19.1)	23 (21.1)	54 (18.4)	21 (18.4)	22 (19.8)
Nasal or oral	33 (8.2)	6 (5.5)	27 (9.2)	10 (8.8)	10 (9.0)
Participants reporting intravenous methamphetamine use ≥1 days in the 30 days before consent — no. (%)	135 (33.5)	39 (35.8)	96 (32.7)	38 (33.3)	36 (32.4)
Intensity of methamphetamine craving‖	66.1±22.3	65.7±22.2	65.8±21.6	66.7±21.3	63.7±21.9
Age of first methamphetamine use — yr	24.8±9.9	24.7±10.7	24.8±9.6	25.5±10.9	24.8±9.1
Other characteristics					
Coexisting cocaine use disorder according to DSM-5 criteria — no./total no. (%)	31/365 (8.5)	9/97 (9.3)	22/268 (8.2)	9/104 (8.7)	9/100 (9.0)
Coexisting opioid use disorder according to DSM-5 criteria — no./total no. (%)	27/370 (7.3)	7/93 (7.5)	20/277 (7.2)	7/109 (6.4)	7/104 (6.7)

Coexisting alcohol use disorder according to DSM-5 criteria — no./total no. (%)	94/293 (32.1)	25/77 (32.5)	69/216 (31.9)	23/85 (27.1)	27/75 (36.0)
Coexisting cannabis use disorder according to DSM-5 criteria — no./total no. (%)	116/318 (36.5)	29/89 (32.6)	87/229 (38.0)	33/86 (38.4)	33/85 (38.8)
Daily nicotine cigarette use — no./total no. (%)	238/337 (70.6)	66/99 (66.7)	172/238 (72.3)	73/89 (82.0)	56/89 (62.9)
Score on PHQ-9 depression scale**	19.9±6.5	19.4±6.5	20.0±6.5	20.1±6.9	19.5±5.9
Score on Treatment Effectiveness Assessment††	18.3±7.2	16.7±7.0	18.6±7.3	18.4±7.5	19.2±7.1
HIV-positive status — no./total no. (%)	90/356 (25.3)	24/92 (26.1)	66/264 (25.0)	24/96 (25.0)	33/105 (31.4)

* Plus–minus values are means ±SD. The intention-to-treat population included all participants who underwent randomization in stage 1 and the participants who underwent randomization again in stage 2. DSM-5 denotes *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, and GED General Educational Development diploma. Percentages may not total 100 because of rounding.

† The total number reflects all participants who underwent randomization in stage 1.

‡ Race and ethnic group were reported by the participants. The "other" category included American Indian or Alaska Native (6 participants), Asian (11 participants), Native Hawaiian or Pacific Islander (2 participants), other (20 participants), multiracial (16 participants), don't know (10 participants), and declined to answer (3 participants).

§ The remaining participants were unemployed, disabled, or retired; were keeping house; were students; or had other status.

¶ The number of days of methamphetamine use at baseline was assessed for the 30 days before informed consent. One participant had only 24 days of assessment. Eligibility required a minimum of 18 days of methamphetamine use at baseline.

‖ Methamphetamine craving (the intensity of the worst craving over the previous week) was assessed at each screening or baseline visit on a visual analogue scale; ratings on the scale, which range from 0 to 100, were averaged to determine a baseline craving, with 0 indicating no craving at all and 100 indicating the most intense craving possible.

** Depressive symptoms were assessed weekly with the use of the Patient Health Questionnaire 9 (PHQ-9); scores range from 0 to 27, with higher scores indicating greater depressive symptoms.

†† Life satisfaction was reported by the participants and was assessed with the use of the Treatment Effectiveness Assessment, which consists of four items; the scores for each item are summed, and total scores range from 4 to 40, with higher scores indicating greater satisfaction.

these results are consistent with those of the primary outcome. The overall treatment effects according to age, ethnic group, race, sex, and trial site are shown in Figure S2.

In the prespecified sensitivity analysis that included participants who provided all four of the expected urine samples in the last 2 weeks of each stage, 28.8% (15 of 52 participants) in the naltrexone–bupropion group and 5.1% (9 of 177 participants) in the placebo group had a response in stage 1; 16.2% (13 of 80 participants) in the naltrexone–bupropion group and 1.3% (1 of 75 participants) in the placebo group had a response in stage 2 (Table S1). The overall treatment effect in this population was an 18.7-percentage-point difference in response (95% CI, 11.6 to 25.8). In the prespecified sensitivity analysis that assumed equal weight for each stage, 16.5% (18 of 109 participants) in the naltrexone–bupropion group and 3.4% (10 of 294 participants) in the placebo group had a response in stage 1; 11.4% (13 of 114 participants) in the naltrexone–bupropion group and 1.8% (2 of 111 participants) in the placebo group had a response in stage 2. The overall treatment effect, under the assumption of equal weight for each stage, was an 11.4-percentage-point between-group difference in response (95% CI, 6.5 to 16.2).

SECONDARY OUTCOMES

The percentage of participants with methamphetamine-negative urine samples was 20.4% in the naltrexone–bupropion group and 12.3% in the placebo group in stage 1 and 19.2% in the naltrexone–bupropion group and 13.4% in the placebo group in stage 2. The weighted difference between the two groups in the percentage of participants with methamphetamine-negative urine samples was 6.8 percentage points (Table 2). The weighted difference between the naltrexone–bupropion group and the placebo group in weekly methamphetamine craving scores on the visual analogue scale was –9.7 points. The weighted difference between the naltrexone–bupropion group and the placebo group in weekly PHQ-9 scores was –1.1 points. The weighted difference between the naltrexone–bupropion group and the placebo group in participant-reported scores on the Treatment Effectiveness Assessment was 4.0 points. There was no prespecified plan for ad-

Table 2. Primary and Secondary Outcomes in the Intention-to-Treat Population.*

Outcome	Stage 1		Stage 2		Treatment Effect	
	Naltrexone–Bupropion (N=109)	Placebo (N=294)	Naltrexone–Bupropion (N=114)	Placebo (N=111)	Weighted Difference	95% CI
Primary outcome — no. of participants (%)†	18 (16.5)	10 (3.4)	13 (11.4)	2 (1.8)	11.1±2.5	—
Secondary outcomes						
Methamphetamine-negative urine samples — %‡	20.4±2.2	12.3±1.6	19.2±2.6	13.4±1.5	6.8±1.7	3.5 to 10.1
Change in methamphetamine craving according to visual analogue scale§	–30.0±3.2	–22.3±1.8	–31.8±3.2	–20.5±1.7	–9.7±2.1	–13.8 to –5.6
Change in score on PHQ-9 depression scale§	–4.8±0.7	–3.3±0.3	–4.4±0.6	–3.7±0.4	–1.1±0.4	–1.9 to –0.2
Change in score on Treatment Effectiveness Assessment§¶	6.5±1.5	2.2±1.0	6.2±1.5	2.5±1.1	4.0±0.9	2.3 to 5.7

* Plus–minus values are means ±SE unless otherwise noted. The total number in stage 1 reflects the number of participants who underwent randomization. The total number in stage 2 reflects the number of participants in the placebo group who did not have a response in stage 1 and therefore underwent randomization again in stage 2. No clinical conclusions can be drawn from secondary outcomes because confidence intervals were not adjusted for multiple comparisons.

† The primary outcome was a response, defined as at least three methamphetamine-negative samples out of four obtained at the end of stage 1 or stage 2. The overall treatment effect was defined as the weighted average of the responses in the naltrexone–bupropion group minus the responses in the placebo group, reported in percentage points ±SE, determined with the use of a weight of 0.43 in stage 1 and a weight of 0.57 in stage 2. The formula for this calculation is provided in the statistical analysis plan, available with the protocol at NEJM.org. The Wald z-test statistic for the primary outcome was 4.530 (P<0.001).

‡ The percentage of methamphetamine-negative urine samples per participant was calculated by dividing the number of methamphetamine-negative urine samples obtained per stage by 12 (the number of expected samples per stage). The treatment effect is the between-group difference in the weighted average of negative urine samples, reported as percentage points ±SE.

§ The changes in stage 1 reflect the change from baseline, and the changes in stage 2 reflect the change from the end of stage 1. The treatment effect is the between-group difference in the weighted average change in scores, reported as the difference in points ±SE.

¶ Data were available for 306 participants in stage 1 (74 in the naltrexone–bupropion group and 232 in the placebo group) and for 196 in stage 2 (98 in the naltrexone–bupropion group and 98 in the placebo group).

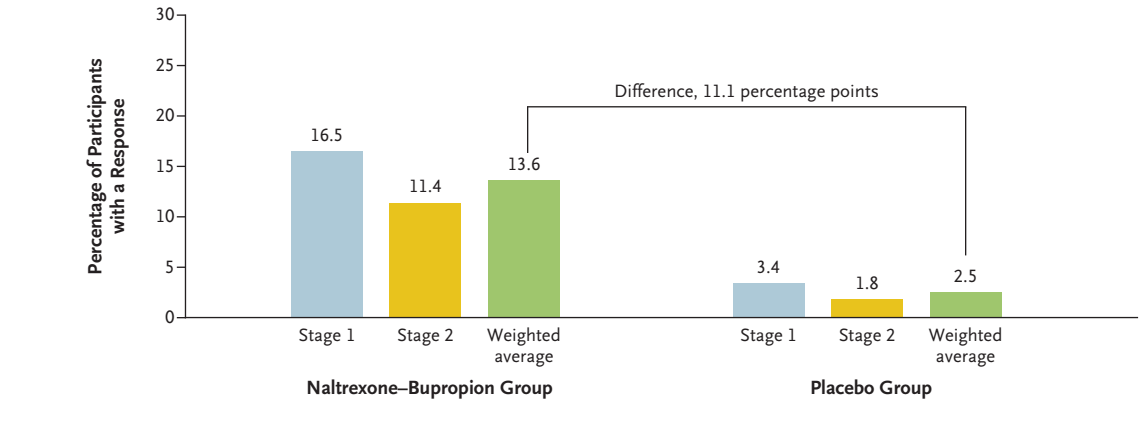
justments of confidence intervals for multiple comparisons of secondary outcomes, and no definite conclusions can be drawn from these results.

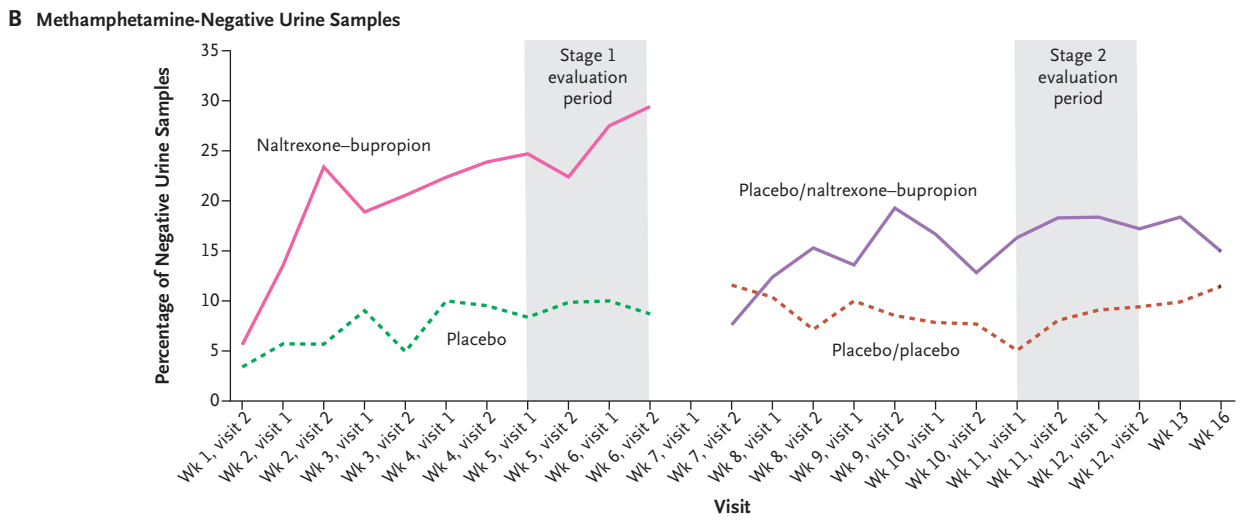
SAFETY

Across both stages, 17 disparate serious adverse events occurred during the trial in the safety population (all participants who underwent randomization): 8 in the naltrexone–bupropion group and 9 in the placebo group. Table 3 includes 13 events that occurred in the intention-to-treat population. The other 4 events (3 in the naltrexone–bupropion group and 1 in the placebo group) occurred during stage 2 in the participants who did not undergo rerandomization. Adverse events were mostly mild or moderate (Table S2). Adverse events that occurred more frequently (P<0.05) with naltrexone–bupropion than with placebo were nausea (37.6% vs. 15.3% in stage 1 and 28.1% vs. 7.2% in stage 2), vomiting (11.9% vs. 2.0% in stage 1 and 10.5% vs. 2.7% in stage 2), constipation (9.2% vs. 2.4% in stage 1), dry mouth (8.3% vs. 1.7% in stage 1), upper abdominal pain (4.6% vs. 0.3% in stage 1), dizziness (10.1% vs. 2.7% in stage 1), tremor (4.6% vs. 0.3% in stage 1), feeling jittery (3.7% vs. 0.7% in stage 1), malaise (3.7% vs. 0.3% in stage 1), hyperhidrosis (7.3% vs. 1.0% in stage 1), and decreased appetite (7.3% vs. 2.0% in stage 1). Complete reports of adverse events are provided in Table 3 and Table S2.

DISCUSSION

The goal of this trial was to assess the effectiveness of the combination of naltrexone and extended-release bupropion in treating methamphetamine use disorder. The primary outcome was a response, defined as at least three meth-





No. of Urine Samples Obtained at Each Visit	Stage 1											Stage 2											
Naltrexone–bupropion	89	96	77	90	73	85	67	81	67	80	68												
Placebo	265	280	229	266	223	260	210	239	203	240	207												
Placebo/naltrexone–bupropion												92	97	85	103	83	96	78	98	82	98	93	98	87
Placebo/placebo												95	106	84	100	82	102	91	99	87	99	85	101	96

Figure 2. Responses and Methamphetamine-Negative Urine Samples.

The primary outcome was a response, defined as at least three methamphetamine-negative urine samples out of a possible four obtained at the end of stage 1 (during weeks 5 through 6) or at the end of stage 2 (during weeks 11 through 12). We calculated the weighted average of the responses in each stage, and the difference between these results was used to determine the overall treatment effect. Panel A shows the percentage of participants with a response and the weighted average of the response in each trial group in the intention-to-treat population, which included all participants who underwent randomization in stage 1 and all participants who underwent randomization again in stage 2. Panel B shows the percentage of methamphetamine-negative urine samples according to stage and trial group in the intention-to-treat population. Placebo/naltrexone–bupropion refers to participants in the placebo group who did not have a response in stage 1 and were assigned to the naltrexone–bupropion group in stage 2. Placebo/placebo refers to participants in the placebo group who did not have a response in stage 1 and were assigned to the placebo group in stage 2. During the 12-week intervention period, participants visited the clinic twice per week, after which they had a visit at week 13 and week 16. The evaluation period was the last 2 weeks of each stage (each evaluation stage is shown in the shaded areas). The number of urine samples obtained indicates the number of urine drug screening results available according to trial group at each visit for all participants in the intention-to-treat population. Results of urine drug screenings obtained at the first visit during week 1 (the day of randomization) are not shown. Results of drug screenings obtained on or before the rerandomization date of each participant in stage 2 are not shown because these samples were obtained when participants were still receiving the regimen assigned in stage 1.

Table 3. Adverse Events That Occurred during the Trial Period.*

Event	Stage 1			Stage 2		
	Naltrexone–Bupropion (N=109)	Placebo (N=294)	P Value	Naltrexone–Bupropion (N=114)	Placebo (N=111)	P Value
Participants with at least one serious adverse event — no. (%)†	1 (0.9)	4 (1.4)	1.00	3 (2.6)	4 (3.6)	0.72
Total no. of serious adverse events‡	1	4		4	4	
Any adverse event — no. (%)	99 (90.8)	245 (83.3)	0.08	88 (77.2)	77 (69.4)	0.23
Adverse events — no. (%)§						
Gastrointestinal events						
Nausea	41 (37.6)	45 (15.3)	<0.001	32 (28.1)	8 (7.2)	<0.001
Diarrhea	7 (6.4)	18 (6.1)	1.00	6 (5.3)	5 (4.5)	1.00
Vomiting	13 (11.9)	6 (2.0)	<0.001	12 (10.5)	3 (2.7)	0.03
Constipation	10 (9.2)	7 (2.4)	0.005	2 (1.8)	3 (2.7)	0.68
Dry mouth	9 (8.3)	5 (1.7)	0.003	1 (0.9)	2 (1.8)	0.62
Upper abdominal pain	5 (4.6)	1 (0.3)	0.006	6 (5.3)	3 (2.7)	0.50
Abdominal discomfort	4 (3.7)	5 (1.7)	0.26	1 (0.9)	2 (1.8)	0.62
Nervous system symptoms and disorders						
Headache	13 (11.9)	68 (23.1)	0.01	11 (9.6)	6 (5.4)	0.31
Dizziness	11 (10.1)	8 (2.7)	0.006	7 (6.1)	1 (0.9)	0.07
Somnolence	3 (2.8)	10 (3.4)	1.00	0	1 (0.9)	0.49
Tremor	5 (4.6)	1 (0.3)	0.006	3 (2.6)	0	0.25
Psychiatric symptoms and disorders						
Irritability	6 (5.5)	19 (6.5)	0.82	5 (4.4)	4 (3.6)	1.00
Anxiety	10 (9.2)	14 (4.8)	0.10	1 (0.9)	1 (0.9)	1.00
Insomnia	6 (5.5)	12 (4.1)	0.59	3 (2.6)	1 (0.9)	0.62
Libido decreased	4 (3.7)	5 (1.7)	0.26	1 (0.9)	0	1.00
Lability affected	4 (3.7)	4 (1.4)	0.22	2 (1.8)	1 (0.9)	1.00
Depression	2 (1.8)	6 (2.0)	1.00	4 (3.5)	4 (3.6)	1.00
General disorders and injection-site reactions						
Fatigue	8 (7.3)	33 (11.2)	0.35	7 (6.1)	8 (7.2)	0.80
Feeling jittery	4 (3.7)	2 (0.7)	0.05	1 (0.9)	0	1.00
Malaise	4 (3.7)	1 (0.3)	0.02	1 (0.9)	0	1.00
Metabolism and nutrition disorders						
Decreased appetite	8 (7.3)	6 (2.0)	0.03	3 (2.6)	3 (2.7)	1.00
Musculoskeletal and connective tissue disorders						
Arthralgia	4 (3.7)	6 (2.0)	0.47	2 (1.8)	0	0.50
Injury, poisoning, and procedural complications						
Contusion	3 (2.8)	5 (1.7)	0.45	0	5 (4.5)	0.03

Table 3. (Continued.)

Event	Stage 1			Stage 2		
	Naltrexone–Bupropion (N=109)	Placebo (N=294)	P Value	Naltrexone–Bupropion (N=114)	Placebo (N=111)	P Value
Skin and subcutaneous tissue disorders						
Hyperhidrosis	8 (7.3)	3 (1.0)	0.002	2 (1.8)	0	0.50

* Events shown for stage 1 include events that occurred before the start of stage 2 in the safety population (all participants who underwent randomization). Events shown for stage 2 include those that occurred on or after the date of rerandomization in participants in the intention-to-treat population (participants who underwent randomization again in stage 2). Adverse events were classified according to the preferred term and system organ class of the *Medical Dictionary for Regulatory Activities*, version 22.1.

† Of the 17 serious adverse events that occurred in the safety population (all participants who gave informed consent), 13 occurred in the intention-to-treat population and are reported in this table. Of the 13 serious adverse events, all except an event of seizure were recorded as serious because they resulted in either inpatient hospitalization or prolongation of an existing hospitalization. The additional 4 serious adverse events occurred after consent was given but before randomization; the events were hypertensive crisis (in 1 participant), genitourinary chlamydia infection (in 1 participant), neurosyphilis (in 1 participant), and appendicitis (in 1 participant). Four additional adverse events occurred in stage 2 in participants who did not undergo rerandomization (3 events in the naltrexone–bupropion group and 1 in the placebo group).

‡ The serious adverse events in stage 1 were substance-induced psychosis, paranoia, pancreatitis, and seizure (in 1 participant each) in the placebo group, and gastroenteritis in 1 participant in the naltrexone–bupropion group. The serious adverse events in stage 2 were gastroenteritis shigella, pneumonia, urosepsis, and being the victim of a crime (in 1 participant each) in the placebo group, and homicidal ideation, cellulitis, neck pain, and hyperglycemia (in 1 participant each) in the naltrexone–bupropion group.

§ The adverse events reported here are events of interest that occurred in 3% or more of participants in either stage in the naltrexone–bupropion group and events that had a P value of ≤0.05 for any pairwise comparison. Table S2 lists all adverse events that occurred during the trial in the safety population.

amphetamine-negative urine samples out of four samples obtained in the last 2 weeks of each stage. The response in each group was calculated by combining the weighted average of the responses in the two stages of the trial. The overall weighted response was 13.6% in the naltrexone–bupropion group and 2.5% in the placebo group. The results of the analyses of secondary outcomes, including the assessment of craving for methamphetamine and improvements in social functioning, were generally in the same direction as those of the primary outcome, but no definite conclusions can be drawn from these data because of the lack of a prespecified plan for multiplicity adjustment of confidence intervals for the point estimates of differences between the two trial groups.

Methamphetamine use disorder is a serious illness and is associated with medical conditions and mental health issues, marked functional impairment, and frequent relapses.[28,29] The participants in our trial were severely affected by methamphetamine use disorder, with almost daily use before entry into the trial. Our definition of a response included valid negative urine samples obtained after only 4 to 6 weeks in each stage of the trial. The percentage of participants who had a response in each stage of the trial was low; however, there was a significant difference in the weighted response (11.1 percentage points) between the naltrexone–bupropion group and the placebo group. The number needed to treat in order for one patient to have a response under the assumptions in this trial is 9.

The strengths of this trial include low attrition, high adherence to the trial regimen, a prospective evaluation to establish illness severity, and an objective primary outcome assessed on the basis of valid urine samples. However, the low attrition and high adherence may limit generalizability to clinical practice. Other limitations include the relatively low representation of women, although the male-to-female ratio in this trial is consistent with the difference in incidences of amphetamine use disorder between men and women in the United States. Adherence to the oral regimen was determined on the basis of participant report and cannot be confirmed because ingestion was not observed by trial clinicians. The results of the trial may be difficult to explain to patients and practitioners because of the sequential parallel comparison design,

which included enrichment of the stage 2 sample with the random reassignment of participants in the placebo group who did not have a response in stage 1 and the use of a weighted combination to analyze the response in each stage. This method was intended to enhance the likelihood of detecting efficacy of the combination treatment. Replication of our trial results in a more naturalistic effectiveness design could be a next step. An additional consideration in interpreting our trial results is the possible continuation of the trial, although the results of the interim sample-size reestimation analysis performed by the data and safety monitoring board showed a significant difference in outcomes between trial groups, and no adjustment was made in the significance level of the test of the primary outcome. The 12-week duration of a trial of a substance use disorder requires consideration of how the treatment can be adapted to practice.

In persons with moderate or severe methamphetamine use disorder, treatment with the combination of extended-release injectable naltrexone and daily oral extended-release bupropion over a period of 12 weeks resulted in a higher response than placebo.

The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or Alkermes.

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APPENDIX

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Los Angeles County Commission on HIV
Services and Best Practices Committee
Service Standards for People Living with HIV in Los Angeles County
Substance Use and Residential Treatment Service Standards Literature and Research Summary

Background

The Los Angeles County Commission on HIV (COH) provides a variety of services for individuals living with HIV. The Standards and Best Practices Committee is tasked with ensuring that all HIV services throughout the county are effective at reaching their target populations, among other responsibilities. In 2021, the committee will update their service standards for home-based case management, benefits specialty, and substance use and residential treatment for people living with HIV. In order to do so, it is imperative to have evidence-based guidelines and recommendations. This literature review will examine existing service standards across different geographical regions in relation to the aforementioned services, with an emphasis on substance use treatment.

COH uses guidance from the Health Resources and Services Administration (HRSA) to provide outpatient services for alcohol and drug disorder treatment. Current services offered are screenings, assessments, and diagnosis. Residential treatment includes services for alcohol and drug treatments in a residential setting and includes pretreatment/recovery programs, harm reduction, behavioral health counseling, medication assisted therapy, neuro-psychic pharmaceuticals, and relapse prevention (Commission on HIV, 2017).

Substance use disorder (SUD) is a significant problem among people living with HIV (Claborn, et al., 2017). For this reason, it is imperative to integrate substance use treatment into HIV care plans. Ideally, substance use treatment among people living with HIV will use interdisciplinary, team-based coordinated care; however, there are structural and systemic barriers to achieving this (Claborn, et al., 2017). A 2017 study examined ways to optimize care coordination of people who have both HIV and SUD by implementing an intervention that combines evidence-based training and mobile technology (Claborn, et al., 2017). The intervention planning occurred in three phases: Phase 1 consisted of qualitative interviews of stakeholders and HIV and SUD treatment agencies; Phase 2 tested the functionality of a tablet-based mobile platform for HIV and SUD treatment providers; and Phase 3 consisted of pre and post test trials with 30 HIV and SUD treatment providers (Claborn, et al., 2017). The information from this study will be used to develop a care coordination intervention using a mobile platform for HIV and SUD treatment providers to create a communication tool across multiple agencies, develop a training protocol, and improve treatment efficacy (Claborn, et al., 2017). This study highlights the importance of joint action in addressing and treating HIV and SUD.

The **Virginia Department of Health** - Division of Disease Prevention, HIV Care Services updated their Substance Abuse Services (Residential) Standards in January of 2019 based on the Health Resources and Services Administration (HRSA) guidelines. Program guidance states that Substance Abuse Services (Residential) are only permitted when a client has a written referral

from a clinical provider as part of substance use disorder treatment funded under the Ryan White program, acupuncture is allowed to be funded under Ryan White only when it is part of the patient's documented plan of a substance use disorder treatment program funded by Ryan White, and program funds may not be used for inpatient detoxification in a hospital setting, unless the facility has a separate license (Virginia Department of Health, 2019). Service standards are divided into the following subgroups: Intake and Eligibility, Key Services Components and Activities, Client Rights and Responsibilities, Grievance Process, Personal Qualifications, Cultural and Linguistic Competency, Privacy and Confidentiality, and Quality Management (Virginia Department of Health, 2019). The service standards along with the appropriate measure for each can be found in the Virginia Department of Health's Substance Abuse Services (Residential) Standards document.

The **Arizona Department of Health Services** Substance Abuse Outpatient Service Standards of Care, last reviewed in July of 2019, provides detailed information on outpatient substance abuse services under Ryan White. Like the Virginia Department of Health, Arizona's program allows acupuncture therapy when it is part of a substance use disorder treatment program funded under HRSA RWHAP (AZDHS, 2019). Syringe access services are permitted as long as they are in accordance with current law and applicable HHS guidance, including HRSA or HAB guidance (AZDHS, 2019). The primary goal of Substance Abuse Outpatient Services is to provide treatment and counseling services to help with substance abuse problems, which will help eliminate barriers to treatment and increase adherence to medical care for people living with HIV who qualify for such services (AZDHS, 2019). The AZDHS lists their service standards, measurements, and goals in full detail on the Substance Abuse Outpatient Services Standards of Care document.

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