Duke University: STYLE 2.0

Implementation Manual

SPNS BMSM Initiative

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STYLE 2.0

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Background

HRSA's Ryan White HIV/AIDS Program (RWHAP) provides a comprehensive system of HIV primary medical care, essential support services, and medications for low-income people with HIV who are uninsured and underserved. The RWHAP funds grants to states, cities/counties, and local community-based organizations to provide care and treatment services to people with HIV (PWH) to improve health outcomes and reduce HIV transmission among hard-to-reach populations.

The intervention outlined in this Implementation Manual was part of the *Implementation of Evidence-Informed Behavioral Health Models to Improve HIV Health Outcomes for Black Men who have Sex with Men (BMSM)* Initiative (otherwise known as the "BMSM Initiative"). This HRSA Special Projects of National Significance (SPNS) Initiative was funded by the HRSA RWHAP, and the intervention was conducted and evaluated within a RWHAP-funded site. The **Strength Through Youth Livin' Empowered 2.0 (STYLE 2.0)** intervention was implemented by **Duke University's Center for Health Policy and Inequalities Research (CHPIR)** based in Durham, NC. SPNS supports the development of innovative models of HIV care and treatment in order to quickly respond to emerging needs of participants served by the RWHAP. SPNS advances knowledge and skills in the delivery of health care and support services to underserved populations living with HIV. Through its demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health related outcomes of treatment models while promoting the dissemination and replication of successful interventions.

Specifically, the three-year BMSM Initiative funded eight demonstration sites (or recipients) to implement evidence-informed behavioral health interventions to engage, link, and retain BMSM living with HIV in medical care and supportive services. The interventions focused on strategies to integrate behavioral health services with HIV clinical care to specifically address the needs of BMSM living with HIV and improve their health outcomes. Each recipient adapted one of four models of care (MOCs) to create an innovative, integrated intervention to serve BMSM living with HIV in their respective community.

Introduction

This Implementation Manual provides guidance on how to adapt and implement Duke University's **STYLE 2.0** in order to facilitate future replication. Among other things, this Manual describes the selected MOC and adaptations, pre-implementation activities, local evaluation, intervention components and implementation experiences, and intervention outputs and outcomes. This Manual also shares lessons learned and best practices to support successful replication of intervention components.

This Manual is designed to provide a broad, concise overview of STYLE 2.0 to a diverse audience of clinical leadership, HIV service providers, and other stakeholders interesting in identifying and implementing new, innovative strategies for improving care for BMSM living with HIV and

other populations in their communities. More detailed information for future replicators can be found in the Implementation Toolkit (see the appendices).

Intervention Overview

Center for Health Policy and Inequalities Research – Duke University

CHPIR is an instigator and facilitator of a broad range of health policy and health disparities research that address policy-relevant issues. Activities focus on population-based health research, health systems research, and intervention and evaluation research. CHPIR fosters an interdisciplinary collaborative investigative environment that also seeks to educate Duke students by providing experiences in working with our research teams and through individual mentorship.

CHPIR is part of the Duke Global Health Institute (DGHI), joining them in their work to reduce health disparities. Together, DGHI recognizes that local is global when addressing health inequalities. In that spirit, CHPIR enhances DGHI's partnerships, research, and impact.

CHPIR is located in Durham, North Carolina (NC), an urban area within the Research Triangle region of NC. STYLE 2.0 partnered with the following organizations around the Triangle area of NC as well as Columbia, South Carolina (SC):

- **Duke University Infectious Diseases Clinic** (Duke ID) – Durham, NC
- **University of North Carolina, Division of Infectious Disease** (UNC) – Chapel Hill, NC
- **University of South Carolina Medical Group, Infectious Disease Division** (USC) – Columbia, SC
- **Lincoln Community Health Center – Early Intervention Clinic** (EI) – Durham, NC
- **Wake County Human Services** (Wake) – Raleigh, NC
- **Advance Community Health** (ACH) – Raleigh, NC

Needs Assessment

Young BMSM (YBMSM) have high rates of HIV infection and poor HIV care continuum outcomes. YBMSM have the highest rates of new HIV infections compared with non-Hispanic White counterparts.[1] Moreover, YBMSM are more likely than young White or Latino men who have sex with men to be to be HIV-infected but unaware of their status.[2,3] Across every stage of the HIV care continuum, including linkage to care, regular engagement in care, uptake and adherence to antiretroviral therapy, and viral suppression, YBMSM with HIV underperform compared to their White peers.[4-6]

The HIV epidemic in NC and SC mirrors that seen throughout the Southern U.S. with young men who have sex with men (YMSM) and particularly YBMSM experiencing the highest rates of HIV diagnoses. In 2019, men who have sex with men (MSM) account for 69 percent of all new HIV infections and the number of diagnoses was highest among persons aged 25-34.[20] Of

these new diagnoses, more than half occurred in the Southern United States.[21] In NC and SC specifically, HIV disproportionately affects BMSM, who account for 61.8 percent and 66.9 percent of all new HIV diagnoses in 2019.[22,23]

MSM in the South face more pronounced issues than those living in other areas, including higher rates of poverty, health disparities, and stigma. Data from among the nine "Deep South" states, including NC, show worse outcomes for PWH, with lower five-year HIV and AIDS survival rates than other geographic regions.[13] As compared to the U.S. overall, PWH in the South are more often people of color, young adults, women, and residents of suburban and rural areas. HIV disparities in the South have been attributed to numerous social, structural, and policy factors including: high levels of racism and poverty; low levels of educational achievement; lack of comprehensive HIV/sex education programs; more rural populations; shortages of HIV medical providers; and increased homophobia and stigmatization of PWH.[13-19]

Adapted Model of Care

Original MOC

As noted above, each recipient adapted and implemented one of four evidence-informed MOCs expected to improve linkage to care, engagement in care, retention in care, and HIV health outcomes and address the comprehensive needs of BMSM with HIV. All of the MOCs were originally developed to improve HIV care and treatment and/or HIV health outcomes for youth and/or adult men of color. CHPIR adapted **Strength Through Youth Livin' Empowered (STYLE)**.[24] Key components of the original MOC include: a medical case manager and peer outreach worker; targeted venue-based and social marketing outreach; a 24-month intervention; and provision of case management and ancillary support services. The following table briefly describes the implementation process of STYLE.

Original Model at-a-Glance	
STYLE	
 Step 1	Create a **social marketing campaign**
 Step 2	Conduct **in-person outreach**
 Step 3	**Obtain referrals** from aligned entities
 Step 4	**Link participants** to medical, behavioral health, and social support network
 Step 5	Offer **virtual support**
 Step 6	Provide regular **care management and ancillary support** sessions

Adaptations

The below table compares the original STYLE components with the *planned* STYLE 2.0 components. Building on the successes of STYLE, STYLE 2.0 planned to add additional in-person components, led by a full time Health Care Navigator (HCN) and a project-specific Behavioral Health Provider (BHP), as well as new virtual components including the STYLE 2.0 healthMpowerment (HMP) app with access to project staff through the app.

Original STYLE Components and Planned In-Person and Virtual STYLE 2.0 Components

Original STYLE Component	STYLE 2.0 (In-person components)	NEW STYLE 2.0 (Virtual components)
A social marketing campaign developed with the input of a Young Adult Advisory Board (YAB) and focus groups	▪ YAB will assist with in-person social marketing campaign adaptations as well as overall program implementation, evaluation, and dissemination ▪ Full access to original STYLE social marketing materials which will be reviewed and adapted as needed based on YAB input ▪ Similar to STYLE, in-person social marketing will include outreach and distribution of materials to locations frequented by YBMSM ▪ Recognition of the original STYLE brand will foster interest and trust among YBMSM	▪ YAB will be convened to provide input on the imagery and content of social media recruitment ads and appropriate sites for engaging YBMSM ▪ Majority of social marketing resources will be dedicated to advertising the project on social and sexual networking sites popular among YBMSM such as Facebook, Craigslist, Grindr, Hornet, Jack'd, and Adam4Adam ▪ Using these strategies will enable us to inform the target population about the intervention and screen individuals for eligibility
Intensified outreach to young Black and Latino MSM youth-serving venues and increased provision of HIV testing services on college campuses, and within the broader community utilizing both venue-based and social and sexual network testing approaches. Strong relationships with NC Disease Intervention Specialists (DIS)/Bridge Counselors assisted with identification of young Black and Latino MSM who had fallen out of care.	▪ Outreach to venues frequented by YBMSM to identify individuals eligible for intervention participation. ▪ Continue to rely on close relationships with Triangle area DIS/Bridge Counselors to identify YBMSM who have never engaged in HIV care or have fallen out of care. ▪ NEW Regional and clinic-based out-of-care lists will be reviewed monthly to identify individuals who may be eligible for the intervention ▪ NEW Monthly meetings with clinic medical staff and support services staff will be held to identify YBMSM at risk of falling out of HIV care	▪ HMP, the online component of the STYLE 2.0 intervention, will provide information about the importance of linkage and regular engagement in HIV care ▪ Program participants will be encouraged to share this information with individuals in their social and sexual networks to facilitate enrollment of other HIV-positive YBMSM ▪ HMP will include a feature allowing out of care YBMSM to directly message either a clinical provider or a HCN to facilitate engagement/re-engagement

Original STYLE Components and Planned In-Person and Virtual STYLE 2.0 Components

Original STYLE Component	STYLE 2.0 (In-person components)	NEW STYLE 2.0 (Virtual components)
A tightly linked **medical–social support network** for Youth newly diagnosed with HIV or reengaging in care that included an infectious disease board-certified physician who oversaw the provision of care to all patients Research team available to participants by phone and text messaging to assist with appointment scheduling or to answer medical questions	▪ NEW Three board-certified infectious disease physicians, each providing services at different clinics that are geographically dispersed within the region, will receive warm handoffs from HCN and provide culturally competent care for YBMSM ▪ HCN will be available by phone and text messaging to assist with scheduling appointments ▪ HCN will schedule and attend clinic appointments with participants ▪ HCN will provide the physician with a summary of participant needs and barriers to care prior to appointments	▪ The physicians will be available to assist with scheduling appointments or answering medical questions through a messaging portal embedded in HMP. Providers will respond to all queries within 72 hours ▪ The HCN and BHP will be available to assist with scheduling appointments or answering questions through a messaging portal embedded in HMP. They will respond to all queries within 48 hours
Provided participants with ancillary social support services, including case management, mental health services, and weekly in-person support groups through a partnership with a local AIDS Service Organization	▪ HCN will give warm handoffs versus simple referrals to behavioral health services, case management services, in-person support groups, and other services to reduce barriers linkage and regular engagement in HIV care	▪ The BHP will provide a 4-session motivation interviewing (MI) intervention for individuals who screen positive for mental health or substance abuse issues or are referred by clinic staff due to mental health or substance abuse concerns. To address barriers to participation, these sessions will be provided via videoconferencing through HMP ▪ The HCN will hold weekly support group meetings via videoconferencing through HMP. Videoconferencing will be used to reduce barriers to participation in the support groups

The following table briefly describes the implementation process of STYLE 2.0 that occurred during the project period.

Adapted Model at-a-Glance	
STYLE 2.0	
 Step 1	Create a **marketing campaign** highlighting program details and enrollment steps; include social marketing as well as community targeted marketing strategies
 Step 2	Network with local organizations and conduct **in-person/virtual outreach** via a word-of-mouth community campaign
 Step 3	**Connect** with local infectious disease clinics and **obtain referrals** from aligned entities
 Step 4	**Link participants** to medical, behavioral health, and social support networks
 Step 5	Offer **virtual support and help build community among participants** through the STYLE 2.0 HMP app and weekly virtual support groups
 Step 6	Provide regular **care management and ancillary support** sessions utilizing the adapted STYLE 2.0 CLEAR protocol

The *implemented* core elements and key characteristics of STYLE 2.0 were as follows: These components are discussed in more detail in the Implementation Activities section below.

- **Outreach:** The HCN actively engaged in the community (e.g., present at community events) and managed the referral network, which included both active and passive referrals from a variety of sources.
- **Medical-social support network:** STYLE 2.0 was supported by a network of board-certified infectious disease physicians, who also represented the clinical partners.

- **Ancillary support services:** STYLE 2.0 linked participants to supportive services (e.g., housing, education, employment, etc.) and additional clinical and behavioral health care, as needed.
- **Virtual components (STYLE 2.0 HMP app):**
  - Forum
  - Health Care Navigator Messaging
  - Knowledge Center
  - Ask the Navigator
  - User Profile
- **Behavioral health:** This included mental health/substance use MI-based interventions (with the BHP) and biweekly support groups (with the HCN).
- **Social marketing campaign and outreach:** While pared down from the original plan, STYLE 2.0 used targeted social media campaigns for bringing awareness of program and also for recruitment into the program.

The major adaptation to the original MOC was adding virtual components of working with HCN and BHP. Providing these services through a virtual setting alleviated various barriers to care such as transportation or taking time off from work or school.

In addition, the STYLE 2.0 HMP app offered an opportunity to build community and provide information focused on the issues most important to the BMSM population. The app was designed to increase safer sex behaviors, promote health and wellness, build community, and create positive norms around HIV, and enabled the intervention to reach geographically or socially-isolated participants. STYLE 2.0 HMP provided users with information and resources, fostered social support, and included game-based motivational elements. The STYLE 2.0 HMP app served as the platform for delivery of virtual intervention components.

The STYLE 2.0 HMP app offered articles in categories including Healthy Living, Living with HIV, Love & Relationships, Great Sex Safer Sex, and Life Skills. Users were awarded badges for posting in the forums, reading articles, completing activities such as quizzes and goal-setting exercises, and leaving likes or comments.

Population Served

Initiative Eligibility Criteria

In addition to the eight demonstration sites, NORC at the University of Chicago was funded under the SPNS BMSM Initiative as the Evaluation and Technical Assistance Provider (ETAP). The ETAP designed and implemented a culturally-responsive, mixed methods evaluation to evaluate the impact of the Initiative across recipients. To be eligible to participate in the multisite evaluation (MSE), a participant was required to be:

- HIV positive;
- Aged 13 and older;
- Identify as a BMSM (including cisgender men, transgender men, and gender non-conforming individuals assigned male at birth); and
- Fit into one of the following categories:
    - Newly-diagnosed/new to care;
    - Never entered into care;
    - Fallen out of care;
    - At risk of falling out of care; and/or
    - Not virally suppressed.

For the purposes of this Initiative, risk factors for falling out of care were ongoing behavioral health issues (e.g., mental health and/or substance use disorders), a history of irregular engagement in care, housing and/or employment instability, a history of sexually-transmitted infections, or a history of negative experiences in a health care setting.

STYLE 2.0-Specific Eligibility Criteria

STYLE 2.0 included young (18-35 years old) Black cisgender men who have sex with men (YBMSM) with HIV in the Triangle region (Durham, Orange, and Wake counties) of NC and the Columbia, SC area. STYLE 2.0 included those who were newly diagnosed/new to care, at risk of falling out of care, or virally unsuppressed.

Pre-Implementation Activities

Organizational and Community Resources

DGHI was established as a University-wide institute to coordinate, support, and implement Duke's interdisciplinary research, education, and service activities related to global health. As part of DGHI, CHPIR's mission is to serve as an instigator and facilitator of a broad range of health policy and health disparities research that address policy relevant issues. CHPIR activities focus on population-based health research, health systems research, and intervention and evaluation research. CHPIR fosters an interdisciplinary, collaborative investigative environment that also seeks to educate Duke students through faculty mentorship and student involvement in research.

Conducting community-based research and evaluation with and within the community grounds CHPIR's work. CHPIR values promoting resources, services, and capacity-building within the community. CHPIR partnerships include: members of target populations, community-based organizations, universities, community- and university-based medical clinics, local and state government entities, and community/church leadership. Leveraging these partnerships and CHPIR's reputation in the community was key to the success of STYLE 2.0 and the ability to bring on various partners around NC and SC.

CHPIR is a seasoned research organization, with many years of collecting sensitive substance use, mental health, and sexual behavior data from HIV-positive individuals through prior studies and additional HIV research. CHPIR's success in data collection comes from training interviewers on interpersonal and sensitive aspects of data collection, as well as research methods; flexibility in the time and location of interviews/surveys; perseverance in scheduling follow-up interviews/surveys; and stringent protocols around the collection and storing of data. Interviewer training includes initial ethics modules with ongoing discussion of ethics, role play highlighting body language in establishing trust and comfort, and diversity training in regards to race/ethnicity, gender, sexual orientation, literacy, and ability/disability. Utilizing this experience and knowledge helped STYLE 2.0 plan for successful quantitative and qualitative data collection with participants.

The STYLE 2.0 team at CHPIR brought extensive intervention, evaluation, and dissemination expertise. The project team was a part of numerous published articles and presentations on various intervention-based research projects. Through these and other HIV projects, the project team brought a wealth of experience in identifying and addressing barriers associated with

access, linkage, and retention for PWH, including YBMSM. This knowledge was incorporated into the development and implementation of STYLE 2.0.

Partnerships

Internal Partnerships

Duke ID, based in Durham, NC, was the internal partner for STYLE 2.0. Duke ID has over 25 years of experience providing medical care for HIV-infected persons. Currently, Duke ID cares for more than 1,800 PWH who receive both primary medical care and HIV specialty services. Retention in care is a major focus and by providing a wide range of services, Duke ID maximizes the likelihood of persons remaining in care. In addition to HIV specialty medical care, patient care services include:

- Social services
- Behavioral health counseling
- Substance abuse counseling and treatment
- Gynecologic care
- Access to clinical research trials
- Pharmacy support

As noted above, Duke ID was an original partner identified in the planning for the STYLE 2.0 project. Per discussions with clinic staff, it was determined that Duke ID would refer participants to the STYLE 2.0 program and work closely with the HCN to support participants enrolled in the program through medical and ancillary care services when needed. It was not a requirement for any participants to attend the clinic at Duke ID, but the co-location of STYLE 2.0 staff on the Duke campus facilitated warm handoffs for the project. Duke ID also provided the BHP included in the STYLE 2.0 program.

External Partnerships

Partners for STYLE 2.0 were recruited in several different ways and at different time, but all ultimately followed a similar general trajectory. The three original partners of Duke ID, the UNC, and ACH were included in the initial discussions of the project development, while Wake and EI were added once the project was funded. After the initial enrollment period of approximately nine months, an additional partner, USC's ID Clinic (also known as Prisma Health), was added to the project in August 2020. The STYLE 2.0 team was able to leverage previous partnerships between USC and Duke's CHPIR and reached out to them for possible partnership in the same way the original NC partners were approached. The partnership followed the same trajectory as the previous partners, including meetings, protocol development, and an official sub-contract between Duke and USC.

STYLE 2.0 leveraged previous partnerships and relationships with medical providers to approach sites about possibly participation in the STYLE 2.0 project. In each case, the project team followed the following steps:

- Project team began with an email to explain the project and request to meet with key representatives at each organization.

- Project team attended an in-person meeting with staff at each organization and shared more details about the proposed project.
- Project team took notes and discussed how the general protocol may need to be tailored for each site.
- Project team and the organization discussed recruitment plans at each site and determined a protocol outline for the project.
- At the end of each meeting, the project team asked if the organization was interested in partnering and what next steps were needed.
    - All sites agreed it was a great project and were willing to partner with STYLE 2.0.
- Each site had their own specific protocol (see Toolkit for example protocol) for developing a partnership.

After meeting and determining next steps, project staff communicated via email to solidify plans for contracts and recruitment/enrollment and project protocols. These were circulated and agreed upon by all partners with the knowledge that, as the intervention rolled out, they may need to be updated. Below is a list of the agreements that were determined to be appropriate for each respective partnership (see Toolkit for example of MOA).

- Duke ID - Created internal sub-contract
- UNC - Created formal sub-contract between Duke/UNC
- USC - Created formal sub-contract between Duke/USC
- EI - Created formal research contract between Duke/Lincoln Community Health Center
- Wake - Created formal partnership letter
- ACH - Signed memorandum of agreement (MOA)

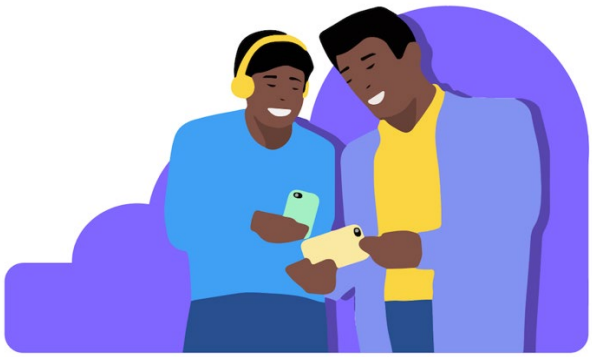
Staffing and Supervision Model

The following table briefly describes the staff background and trainings for the STYLE 2.0 team. Please see the Toolkit for the HCN job description.

Staff Backgrounds and Trainings	
Health Care Navigator (2)	• Bachelor's and/or Master's Degree in Public Health field • Trainings: Medical Case Management, HIPAA, Discrimination and Harassment, Mental Health First Aid, and procurement card training • Counseling Testing and Referral training through NC DHHS • Centers for Disease Control and Prevention (CDC) Certification: Choosing Life: Empowerment! Action! Results! (CLEAR): CLEAR *is an evidence-based, health promotion intervention for males and females ages 16 and older with HIV. CLEAR is a client-centered program delivered one-on-one using cognitive-behavioral techniques to change behavior.*
Behavioral Health Provider (1)	• Licensed Clinical Social Worker (LCSW) • Licensed Clinical Addiction Specialist (LCAS) • 10 years of experience working as a behavioral health and substance use counselor for individuals with HIV at Duke ID.
Management	• Graduate-level degree in related public health/social work-related field. • Experience managing multiple intervention research projects, including over eight years working with target population**.**
Medical-Social Support Network (3)	• Board-certified infection disease physicians, representing three HIV-care clinics in the intervention region. • Chosen based off of expertise and involvement with target population.

Marketing and Promotion

The first STYLE 2.0 HCN attended many community meetings and became a well-known voice for BMSM. Duke simultaneously created engaging **flyers and palm cards** based on regular YAB input. These flyers were displayed in clinics and palm cards were given to clinic staff to distribute to potential participants. Throughout these recruitment activities, Duke was able to leverage brand recognition of the initial STYLE intervention, which was implemented nearby at UNC in Chapel Hill, NC.



STYLE 2.0 graphics created using YAB feedback.

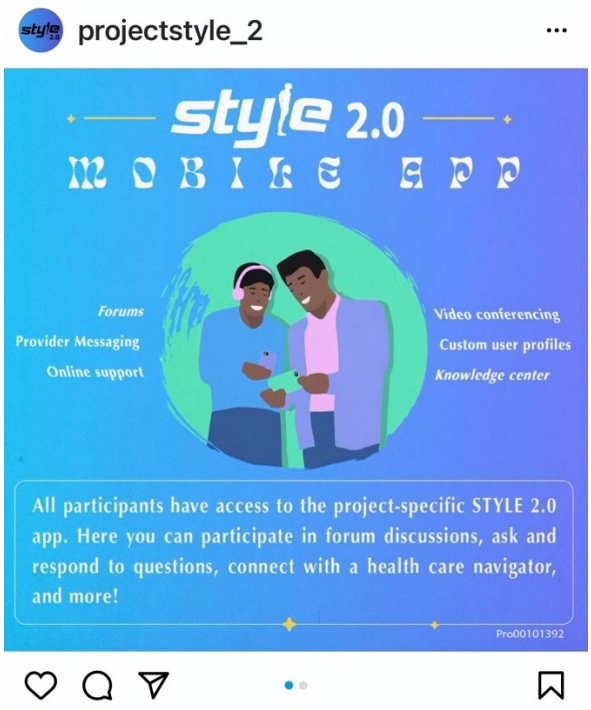
Recruitment Activities:

The HCN was responsible for ensuring both active and passive referrals to STYLE 2.0 from the following sources:

- Clinic and regional out of care lists
- Medical/support staff meetings
- Social marketing and media campaign responses
- YAB recruitment activities
- Flyers at various community locations
- HCN attendance at community events and meetings

At Prisma Health, a Community Health Worker conducted in-person referrals and warm-handoffs to potential participants throughout the coronavirus disease 2019 (COVID-19) pandemic. In addition, this person reached out to individuals out of care and not seen in the clinic through phone calls and emails to share the program opportunity. This yielded the highest enrollment for the study. All other in-person recruitment activities were not permitted (beginning March 2020) due to COVID-19.

Lastly, project staff created a small-scale **social media campaign** consistent with the design of the STYLE 2.0 print recruitment materials. Staff connected with other research centers within DGHI to share the STYLE 2.0 Instagram content on their accounts to increase engagement.



Local Evaluation

Local Evaluation Overview

STYLE 2.0 Evaluation Design

Evaluation of the STYLE 2.0 intervention helped to determine the effectiveness of the intervention in improving primary and secondary intervention outcomes among STYLE 2.0 participants. The evaluation used a mixed-methods approach, integrating both quantitative and qualitative methods. This allowed the STYLE 2.0 team to assess significant changes in biological and behavioral outcomes as well as assess the context in which these changes occurred and the processes involved in achieving these outcomes.

Multisite Evaluation

The MSE assessed implementation processes, intervention services and participant-level outcomes, and intervention costs. Self-reported participant survey data, encounter data, and clinical outcomes data collected for the MSE were available for analysis in local evaluations.

- Evaluation to determine the effectiveness of the intervention in improving:
  - Primary intervention outcomes
    - linkage to HIV care
    - regular engagement in care
    - antiretroviral uptake and adherence
    - viral suppression
  - Secondary intervention outcomes
    - mental health
    - substance abuse
    - stigma
- Mixed-methods approach - integrating both quantitative and qualitative methods
    - Allow to assess significant changes in:
      - biological (i.e., viral load) outcomes
      - behavioral (e.g., engagement in care, substance abuse) outcomes
      - assess the context in which these changes occur
      - assess the processes involved in achieving these outcomes

Quantitative Evaluation – The STYLE 2.0 quantitative evaluation included self-reported survey data, including both local evaluation questions and the MSE evaluation questions. Survey data was also collected from participants at baseline, 6- and 12-months using Qualtrics. Lastly, paradata from STYLE 2.0 HMP app component was used to identify the dosage and specific components of online interventions that are associated with changes in outcomes.

Qualitative Evaluation – STYLE 2.0 staff conducted approximately 1-2 qualitative interviews with a cohort of intervention participants (n=20) conducted at baseline and/or 6- and/or 12-months post-baseline. These interviews gathered information about barriers and facilitators to HIV care as well as information on ways the STYLE 2.0 intervention may have influenced behavior over time. Approximately 10 semi-structured interviews with HIV medical care and support services providers to elicit opinions about the design, implementation, and results of the project at the close of the project (see Interview Guide in Toolkit).

Process Evaluation – The process evaluation included information such as quarterly reports, monthly budget meetings, monthly conference calls, study procedure, and training manuals.

Intervention Logic Model

Planning			Implementation		Outcomes	
Goals of Project	**Assumptions**	**Inputs**	**Target Population**	**Activities**	**Outputs**	**Outcomes**
▪ Goal 1: To adapt the original STYLE intervention to create STYLE 2.0. ▪ Goal 2: To implement STYLE 2.0 with at least 100 HIV+ YBMSM who have never entered care, fallen out of care, or at high risk of falling out of care to increase linkage to care, retention in care, antiretroviral uptake & adherence, and viral suppression. ▪ Goal 3: To evaluate the effectiveness of STYLE 2.0 for: 3a) increasing linkage to care, retention in care, ART uptake & adherence, and VS; 3b) reducing HIV care continuum barriers ▪ Goal 4: To transfer knowledge and skills to permanent clinic staff, local, state, and federal entities for sustainability and long-term community benefit.	▪ Increasing linkage to care, engagement in care, ART uptake & adherence, and viral suppression among HIV+ YBMSM will improve overall health and decrease onward HIV transmission. ▪ Barriers to linkage and engagement in care (i.e., individual, interpersonal, social, structural) must be addressed by the intervention to improve outcomes. ▪ Addressing substance abuse and mental health disorders will improve outcomes.	▪ $300,000 grant x 3yrs ▪ Project staff (key personnel, Medical Advisory Team member (co-investigator), Health Care Navigator, Behavioral Health Counselor) ▪ Project consultants (Hightow-Weidman, Swygard, One Cow Software) ▪ Partner clinics and staff (Duke ID, UNC ID, USC ID, Advanced Community Health) ▪ Community partners ▪ Original STYLE intervention materials	▪ HIV+ YBMSM (aged 18-35) who reside in the Triangle region of NC and either: 1) Have never entered HIV care 2) Have fallen out of HIV care 3) Are at risk of falling out of care	▪ Convene YAB meetings to inform intervention adaptation, implementation, and evaluation ▪ Consult with Dr. Hightow-Weidman on intervention adaptation ▪ Hire and train Health Care Navigator ▪ Adapt original STYLE intervention to create STYLE 2.0 (e.g., adapt social marketing campaign for social networking sites, adapt HMP online intervention, develop motivational interviewing component to address MH/SA) ▪ Develop intervention protocols ▪ Recruit, enroll, and retain STYLE 2.0 participants ▪ Collect and analyze process and outcome evaluation data ▪ Transfer knowledge and skills to other staff ▪ Disseminate intervention materials and findings to larger research and practice community	▪ STYLE 2.0 intervention ▪ STYLE 2.0 implementation protocols ▪ Trained Health Care Navigator and Behavioral Health Counselor ▪ 100 YBMSM recruited, enrolled, and received STYLE 2.0 ▪ Quantitative and qualitative data and findings ▪ Intervention dosage data ▪ STYLE 2.0 replication package ▪ Dissemination of findings and replication package ▪ Knowledge transferred to other staff	**Intermediate Outcomes (achieved by 12-month assessment)** • Increase the proportion of participants with behavioral health issues who receive behavioral health services by 75% • Increase the proportion of participants who have never received HIV care who are linked to care by 90% • Increase the proportion of participants in regular care (at least 2 visits for routine HIV medical care in 12 months at least 3 months apart) by 75% • Increase the proportion of participants with undetectable viral load by 20% **Long-term Outcomes** • Reduce HIV-related health disparities among HIV+YBMSM • Decrease morbidity and mortality related to HIV among HIV+YBMSM

Implementation Activities

Core Components

Individual-Level Core Intervention Activities

STYLE 2.0 consisted of several options of intervention activities for participants enrolled in the program. Apart from enrollment and evaluation, intervention components were all optional. While these components, including CLEAR session(s) with the HCN, STYLE 2.0 app use, virtual support groups, and behavioral health services, were encouraged, none were mandatory to be included in the STYLE 2.0 program.

Activity 1: Enrollment – Checklist of activities for first meeting with HCN
The HCN verified enrollment criteria was met and shared various aspects of the project to potential participants prior to enrollment. The HCN then completed the enrollment checklist. See the Implementation Toolkit for the Screeners and Enrollment Checklist.

Activity 2: Behavioral Health Services – MI
The brief MI component of STYLE 2.0 (four sessions delivered over 8-10 weeks) focused on readiness to enter or regularly engage in HIV care and key psychosocial barriers that impact utilization of these services such as substance abuse, mental health issues, and lack of social support.

These occurred virtually and, once completed, the BHP referred the participant to continued mental health or substance use services, if needed (see MI Protocol in Toolkit).

Activity 3: STYLE 2.0 Adapted CLEAR Protocol – Choosing Life: Empowerment! Action! Results! (CLEAR)
The HCN followed the adapted, CDC-developed CLEAR Protocol for the first six months of the intervention when meeting with participants. Depending on the level of need, the HCN met with participants on a bi-weekly or monthly basis. They followed the STYLE 2.0 CLEAR manual and implemented the session activities and tools per the corresponding timeline (see adapted CLEAR Protocol in the Toolkit).

Activity 4: Referrals for supportive services – HCN
The HCN referred participants to various services as needed throughout the project period. These included but were not limited to:

- Housing
- Education
- Employment
- Child Care
- Support groups
- Alternative medicine

Activity 5: Transportation to medical and ancillary care appointments – HCN
The HCN addressed transportation needs for both medical and ancillary care services, as needed. This included providing bus passes, helping to secure Medicaid transportation, helping secure a bus pass and providing training on navigating the bus routes and schedules, and working with clinics to provide medical Lyft or Uber rides.

Activity 6: Communication with Medical Provider – HCN
The HCN communicated with HIV medical providers with and on behalf of participants. This was on an as-needed basis. The HCN also offered to attend medical appointments with the participant if needed.

Activity 7: Virtual support groups – HCN
The HCN led virtual support groups on a weekly basis. These groups consisted of general support group meetings and educational topics as determined by the HCN such as wellness activities, medication and appointment adherence, financial management, and other topics suggested by the group. The groups were held each week in a private Zoom meeting room, participants could choose to share their video or keep it off, groups provided a general check-in for participants and if participants had no specific topics they wanted to discuss, the leading HCN would suggest a topic for discussion and at times provide education on that topic.

Activity 8: STYLE 2.0 HMP App – HCN
The HCN enrolled participants into the STYLE 2.0 HMP app and monitored content uploads to the application. The app provided a platform for members of the STYLE 2.0 community and staff to engage and interact.

Systems-Level Core Intervention Activities

Regular meetings with partner sites helped to keep both the HCN and the clinic providers apprised of additional participant needs and participation in STYLE 2.0 activities. This not only created a space for communication and engagement between the STYLE 2.0 team and partner sites, but it also helped to increase engagement and buy-in from partner sites. Regular meetings allowed team members to utilize community organizations and partners in order to achieve better health outcomes for individuals living with HIV.

In addition to partner site meetings, internal STYLE 2.0 team meetings occurred twice weekly. One meeting focused on project logistics and any additional “business”, while the other meetings were case conferences where the HCNs presented on various cases they were working on and the group discussed any questions or additional resources they had to offer.

The YAB reviewed and provided feedback on a wide range of STYLE 2.0 materials (e.g., logos, advertising materials, app content, protocols, and surveys) to determine ways to optimize the material for YBMSM. The YAB formed prior to any engagement in project activities in order to obtain feedback on all aspects of project prior to implementation. Enrollment in the YAB fluctuated between 3-7 members throughout the project period. Members attended 1-2 hour-

long meetings as needed, generally on a monthly basis, and received a $35 e-gift card as compensation for their participation.

Behavioral Health Integration

STYLE 2.0 behavioral health components included the following:

- SAMISS screener at intake and six months
- HCN referrals to the BHP for MI sessions
- Referrals to additional behavioral health services
- STYLE 2.0 HMP app
    - Mental health/substance use-focused content
    - Health empowerment
    - Social support
- Virtual support groups

After the HCNs met with the participants for CLEAR sessions, they met with the BHP regularly for a debriefing. This was to ensure participants were not showing mental/behavioral health concerns (e.g., symptoms of depressions, anxiety, suicidal ideation, substance misuse, etc.) while in the presence of the HCN. If there were concerns, the BHP made a referral to other resources to help the participant.

The HCN also provided a warm handoff to the BHP for participants who screened positive for behavioral health services, using a three-way video conference or phone call to introduce the BHP. The BHP followed the following protocol to deliver a series of four virtual MI sessions:

> **Overview:** These participants were seen via virtual appointments or phone calls for four sessions over a period of 8-10 weeks.
>
> **General Goals:** Each participant was assessed for diagnostic criteria related to mental health disorders and substance use disorders. Stabilization of active symptomatology and safety concerns was addressed before programmatic goals were considered. General goals included increasing readiness to enter or regularly engage in HIV care and identifying and addressing the key barriers that prevent such engagement.
>
> **Safety:** If safety concerns exist related to active or acute suicidal and/or homicidal ideation, intent, or plan, safety measures were employed. Depending on the presentation of the participant, interventions included verbal or written contracting, referral to an acute psychiatric or substance abuse triage or treatment setting, or the use of law enforcement was initiated.

MOTIVATIONAL INTERVIEW SESSION OVERVIEW

Session 1: The participant was provided an overview of the MI approach and assessed for their readiness to change. The Stages of Change was referenced. Specific barriers that impeded engagement in HIV, mental health, and/or substance abuse care were identified.

Session 2: The participant continued to explore psychosocial barriers that impeded change by having an individual or cumulative effect on readiness or commitment to HIV, mental health, and/or substance use care. Collaborative goal-setting occurred.

Session 3: Continued to explore change state and assist participant in increasing readiness for change or commitment to change. Primary areas of exploration included barriers to change and participation in clinic-based HIV, mental health, and/or substance use care.

Session 4: The final session reviewed the progress made towards treatment goals and included additional discussion about the relationship between the participant's psychosocial barriers and readiness to enter or regularly engage in HIV, mental health, and/or substance use care. The session also addressed termination issues and transition to clinic-based mental health and/or substance use services. Discharge goals were also discussed as well as exploration or self-efficacy to meet goals.

The HCN also led weekly online support groups. The weekly virtual support groups created a safe space for participants to share, listen, and discuss community and individual experiences.

In addition to referrals for behavioral health services from the HCN, the STYLE 2.0 HMP app featured articles and quizzes on subjects including safe vs. unsafe alcohol consumption, addiction support services, and coping with a loved one's addiction.

COVID-19 Adaptations

While STYLE 2.0 was always planned to include virtual components, COVID-19 forced all aspects of the project to be conducted virtually. STYLE 2.0 project staff created virtual protocols for recruitment, enrollment, and support groups.

COVID-19 Impact		
 Recruitment	 Program Delivery	 Evaluation & Data Collection
• Created new **partnership with USC**, which continued in-person clinic recruitment and warm handoffs. • Created a **small-scale social media campaign** on Instagram. Utilized internal connections at DGHI to share the intervention on social media pages.	• HCN engaged in weekly, bi-weekly, or monthly **virtual/phone check-ins** with participants based on individual need. • Originally, HCN planned to provide transportation assistance to medical and ancillary care services to participants as needed. Due to COVID-19, HCN were unable to provide this form of support. As a result, HCN conducted **more frequent and in-depth virtual check-ins** and increased focus on **connecting participants to tailored support services** (e.g., rent assistance, local food banks). • **Regular virtual support groups** became a foundation of the community and were the only support groups conducted through STYLE 2.0. Original programming allowed for the possibility of in-person support groups. Hosted 1-3 times per week, support groups offered a space for open-ended discussion surrounding topics including spirituality in the LGBT+ community, the media vs. reality, and dating with HIV. • To foster stronger community in absence of in-person, greater emphasis was placed on **STYLE 2.0 app engagement.** Specific app engagement activities included sharing resources, creating engagement activities (e.g. quizzes and goal-setting tasks), and App Lotteries, where participants won $20 gift cards for sparking discussions in the app.	• Updated **quantitative evaluation** to emailing a link for all participants to complete the survey, rather than having the option to complete these in person. • **Qualitative interviews** conducted with participants through Zoom and telephone calls. To learn more about individual program experiences, interviewees were contacted for a follow-up interview 6-12 months after their first interview.

Costs

The following demonstrates the staffing and cost needs in order to replicate the STYLE 2.0 program as outlined above:

- Full-time salaried HCN position with a minimum of a bachelor's degree in the field of public health. Cost considerations include an office space, computer, and organizational tools, such as a portable tablet for assessments.
- Percentage of a Licensed Clinical Social Worker salary for behavioral health support. Amount would be dependent upon enrollment numbers, but approximately 10-25% effort.
- Percentage of a medical provider salary, for expertise and oversight of participant health needs. Approximately 5% effort.
- Percentage of a master's degree-level program manager salary to help guide project team. Approximately 25% effort.
- Percentage of project coordinator effort to help upload STYLE 2.0 app content and monitor app engagement. Approximately 25% effort.
- Office space rental for approximately five employees and overhead.
- This project does not require an evaluator or data analyst.

Intervention Outputs and Outcomes

Intervention Outputs

The mean age for STYLE 2.0 participants was 27.7 years (range: 17-35). The majority of participants identified as gay (69.7 percent) and 23 percent had at least some college education. A third of the sample (33.3 percent) reported a yearly income of $5,000 or less. Slightly more than half (54.5 percent) lived in NC.

A total of 66 participants enrolled in STYLE 2.0, and 12 of those individuals were newly diagnosed. Of those 12 participants, 91.7 percent (n=11) attended a routine HIV medical care visit within three months of their HIV diagnosis. All other HIV outcomes improved from baseline to 12-month follow-up, including receipt of HIV care (78.8 percent to 84.9 percent), retention in HIV care (75.9 percent to 87.7 percent), being prescribed ART (96.8 percent to 98.5 percent), and achieving viral suppression (82.3% to 90.8%). In general, participants' behavioral health outcomes improved over the intervention period.

Lessons Learned and Best Practices

Implementation

Challenges and Lessons Learned

Due to the expense of advertising on social/sexual networking platforms, Duke did not initially recruit participants via social media. Instead, Duke first relied on referrals from their clinical partners and community organizations.

When Duke originally presented STYLE 2.0 to their clinical partners, there was a lot of buy-in and excitement. However, Duke had to wait six months to launch, so the momentum died down and Duke had to build it back up. **To keep momentum, be ready to enroll when initially sharing the intervention.**

The launch of the STYLE 2.0 HMP app was delayed. Duke experienced a change in the developer, the format of the platform, and the funding available for the platform during the first project year. As a result, Duke launched STYLE 2.0 on 9/28/19 in a pilot phase without the app. Be flexible with intervention enrollment timing and plan for an extended timeframe for developing key intervention components, such as a mobile app.

Facilitators and Best Practices

Throughout the entire program, YAB oversight helped ensure community input on STYLE 2.0 components, including recruitment materials, support group structure, and STYLE 2.0 app content. Creating a community was an important aspect of the program for both the YAB participants and the program participants.

Word-of-mouth community campaigns are critical for program enrollment, and HCN exposure to clinic staff can lead to strong program support from an entire clinic. In addition, in-person clinic recruitment with a warm handoff yielded the highest likelihood of enrollment in the program. Virtual warm handoffs proved effective as well, especially between HCN and the STYLE 2.0 BHP.

IMPLEMENTATION	
Challenges/Lessons Learned	Facilitators/Best Practices
Word-of-mouth via community campaigns is a critical and effective enrollment strategy.	**Keep the momentum going by being ready to enroll when sharing the intervention.** STYLE 2.0 was not ready to enroll when presented to the community and then hit more slowdowns with IRB and Certificate of Confidentiality delays. Excitement waned and the team needed to present the project again six months later to restore momentum.
During COVID-19, because the STYLE 2.0 team was not present in clinics, partner clinics saw a decrease in enrollment. USC alone had an in-person staff member recruiting for STYLE 2.0 and was the only STYLE 2.0 partner who had an increase in referrals and enrollment during the COVID-19 pandemic.	In-person recruitment at the clinic with a warm handoff yields the greatest chance of enrollment.
Ensuring target population input consistently throughout the entire duration of the project is critical for success.	Creating an advisory board with target population community members, hosting regular monthly meetings for members, and providing compensation for involvement is essential for an effective intervention.
Community networking is important for program sustainability.	By building strong relationships with local LGBT+, Black leadership, and HIV/AIDS organizations, the HCN can create opportunities for project participants to continue to engage with the community once the project ends.

Evaluation

Challenges and Lessons Learned and Facilitators and Best Practices

The evaluation of STYLE 2.0 included surveys, interviews, and medical chart reviews. One challenge with the STYLE 2.0 evaluation was the length of the survey. In addition to the ETAP survey questions for the MSE, the STYLE 2.0 patient survey included additional survey questions for the local evaluation. While this resulted in a more robust data set, it was cumbersome to participants. In the future, it is important to weigh the burden of the survey length and the need for the information gathered.

COVID-19 switched all program components to virtual, including compensation for participating in the research evaluation activities. The STYLE 2.0 program was flexible in the gift cards it provided and often was able to tailor this to the need of the participant. However, several local grocery store chains were not able to provide online gift cards, and this made it difficult to provide tailored compensation for research to all participants.

Lost to follow-up is a problem many researchers face. One challenge associated with this is that participants who were not engaged with STYLE 2.0 were harder to engage in the research aspect as well. We learned that if HCN could engage the participant in the research activities at the time they were communicating with the participant (e.g., texting or talking via phone call in real-time), they were much more likely to complete the surveys.

The importance of qualitative research cannot be overlooked. The interviews conducted through STYLE 2.0 offer context to the outcomes numbers and also offer anecdotes that otherwise would be lost in the numbers of quantitative data presentation.

EVALUATION	
Challenges/Lessons Learned	Facilitators/Best Practices
Longer survey length reduces the likelihood of completion.	Keep survey length in mind when drafting questions.
Due to COVID-19, the project had to limit the incentives to online access. Some participants would have benefitted from other types of incentives that do not work digitally (e.g., grocery store gift cards)	Offer a wider range of incentive gift cards to best meet participant needs. Specifically, offer grocery store cards and fuel gift cards in addition to generic Amazon and Target gift cards if possible.
It is easier to get someone who is engaged to complete evaluation activities.	If unable to utilize project staff for evaluation, ensure that the evaluator is included in regular team meetings to have a greater understanding of the intervention.
Qualitative evaluation gives a more robust picture and puts quantitative data into context.	Qualitative data can add a new dimension/component to other data being collected. Hearing a range of participant experiences paints a fuller picture of intervention successes and shortcomings that cannot be captured in quantitative data.

Dissemination Activities

To Learn More

Dullabh, P, Glotfelty, J., LeGrand, S., & Tingwane, A. (2020, August 11-14) *Using Innovative Technology Strategies to Engage BMSM Living with HIV in Care* [Oral presentation]. 2020 National Ryan White Conference on HIV Care and Treatment, Washington, D.C. https://ryanwhiteconference.hrsa.gov/Parnell, H., LeGrand, S., Goings-

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