Peer Health Navigation Intervention Overview

HPTN 091 Peer Health Navigation Intervention

Overview

This section provides a roadmap for the Peer Health Navigation (PHN) Intervention in HPTN 091.

The HPTN 091 PHN intervention integrates evidence-based strategies from Strengths-Based Case Management (SBCM) and Healthy Divas (HD).

- **Strengths-Based Case Management (SBCM)** is an intervention that identifies the unique strengths of individuals to help link and navigate them to gender-affirming health and social services.

- **Healthy Divas (HD)** is a peer counseling intervention designed "by" and "for" transgender women that promotes positive change and enhances gender affirmation.

The components of the PHN intervention and implementation procedures are described below.

Who is a PHN in HPTN 091?

The PHN is a person who shares the same experiences and community membership as participants, and who is trained to provide linkages to gender-affirming health and social services in order to mitigate contextual barriers and enhance facilitators to PrEP uptake and adherence.

For HPTN 091, a peer is a transgender woman. This definition is based on feedback obtained from community consultations cross each of the sites, from the community advisory board, and from community members to inform the HPTN 091 study.

PHN Screening, Enrollment, and GAHT Initiation

Figure 1 illustrates the screening procedures for potential participants. Once a participant is considered eligible through screening, an enrollment visit will be scheduled. **Figure 2** shows the enrollment visit procedures. **Figure 3** shows the timeline for the second PHN session after the GAHT initiation visit.

Figure 1. Screening Procedures Flow Chart

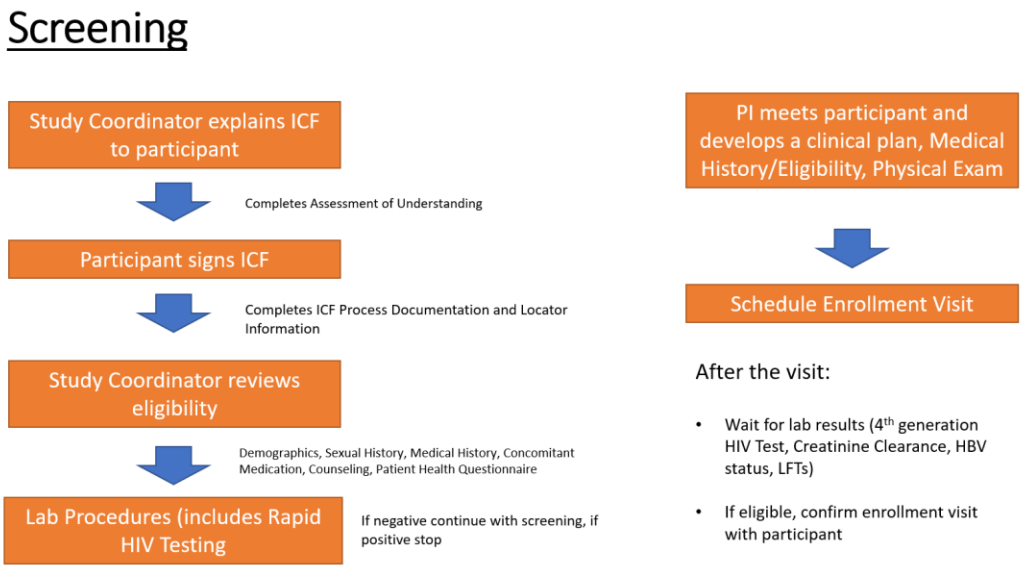


Figure 2. Enrollment Procedures Flow Chart

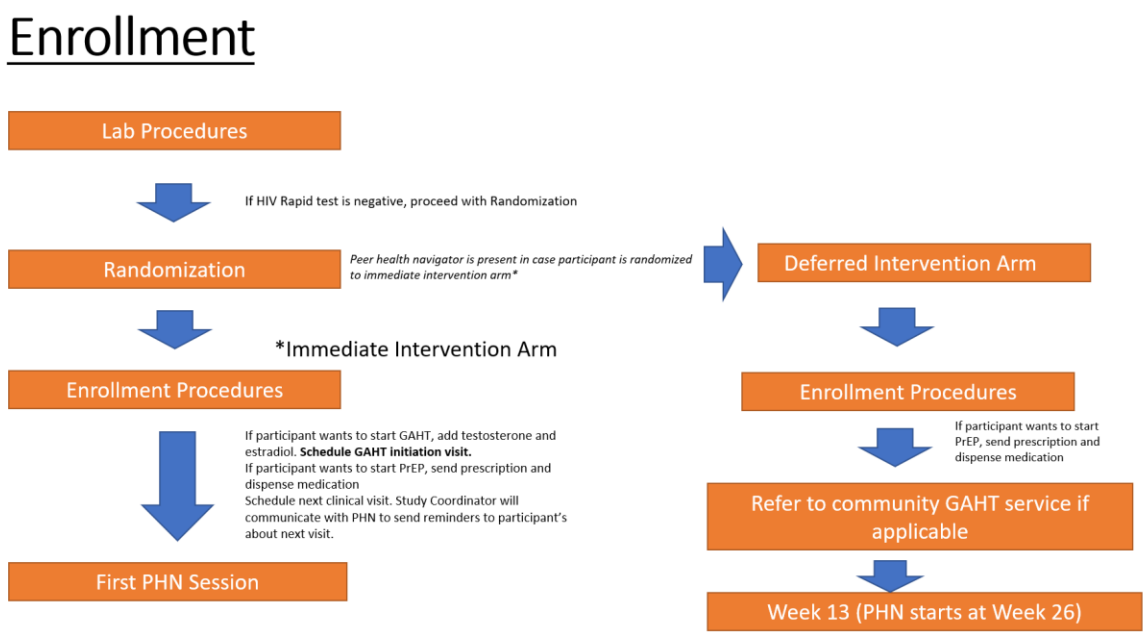
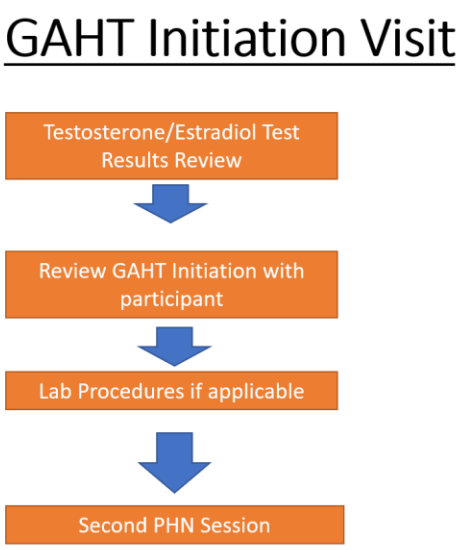


Figure 3. GAHT Initiation Visit Timeline



PHN Intervention Structure

If randomized to the immediate intervention arm, participant will meet PHN at their enrollment visit and complete session one. PHNs document interactions with participant's on "Encounter Summaries". These not only include the session but any other interactions with participants – phone calls, in-person warm handoffs to services, telehealth, etc.

PHNs will keep documentation on a PHN binder separate from participant's research chart. PHN will keep a log with PHN intervention sessions completed.

The PHN intervention is comprised of 6 individual sessions delivered one-on-one between the PHN and the participant. Sessions are delivered approximately monthly for 6 months. Each session is structured and lasts approximately 60 minutes, depending on the specific content in the session being delivered. Following completion of the 6 sessions, participants have a monthly PHN brief check-in for the remaining duration of the study.

Table 1 presents the frequency and timing of PHN sessions in relation to study visits for the Immediate Intervention Arm and the Deferred Intervention Arm. In the first 6 months, the Immediate Intervention Arm will begin PHN sessions immediately after completion of the enrollment visit. PHN sessions will be completed in 6 months.

In the first 6 months, the Deferred Intervention Arm will receive standard of care linkages at study visits from research staff who are not the PHN and when requested by the participant. Following completion of their 6 mo f/u visit, the Deferred Intervention Arm will begin PHN sessions. PHN sessions will be completed in 6 months.

Table 1. Frequency and Timing of PHN Intervention Sessions

Month	Visit	Immediate Intervention Arm	Deferred Intervention Arm
0 mo	Enrollment	Session 1	Linkage
1 mo		Session 2	
2 mo		Session 3	
3 mo	3 mo f/u	Session 4	Linkage
4 mo		Session 5	
5 mo		Session 6	Linkage
6 mo	6 mo f/u	PHN check-in	Session 1
7 mo		PHN check-in	Session 2
8 mo		PHN check-in	Session 3
9 mo	9 mo f/u	PHN Check-in	Session 4
10 mo		PHN Check-in	Session 5
11 mo		PHN Check-in	Session 6
12 mo	12 mo f/u	PHN Check-in	PHN Check-in
13 mo		PHN Check-in	PHN Check-in
14 mo		PHN Check-in	PHN Check-in
15 mo	15 mo f/u	PHN Check-in	PHN Check-in
16 mo		PHN Check-in	PHN Check-in
17 mo		PHN Check-in	PHN Check-in
18 mo	18 mo f/u	PHN Check-in	PHN Check-in

At any time point corresponding with a study visit, the PHN intervention session should be delivered after any study visit procedures. For example, a 3 month f/u visit should be completed prior to the PHN session being delivered. The PHN session may be completed on the same day as the visit and must be completed within 2 weeks.

After each PHN Session, PHNs complete a Session Summary Document and their PHN Session Log. They make a copy and give it to the study coordinator who will file it on the participant's chart and enter it on Medidata. The session content is kept on a PHN Session binder created for each participant (different from the participant's research chart).

PHNs meet weekly with their supervisor to review documentation and prepare sheets for future sessions. These encounters may also include roleplaying for practice sessions, addressing participant's issues and a temperature check for the PHN as well.

Conceptual Frameworks in the PHN Intervention

The PHN intervention is conceptually grounded in Hierarchy of Needs and Gender Affirmation frameworks.

The hierarchy of needs is shown as a pyramid with the largest, most fundamental level of needs at the bottom (e.g., physiological, safety), and psychological and self-fulfillment needs at the

tope (e.g., belongingness and love, esteem, self-actualization) (see **Figure 4**). Maslow's theory suggests that at any given time a certain need "dominates" the human organism, and that the most basic needs must be met before the individual will strongly desire (or focus motivation on) the secondary or higher-level needs.

Gender affirmation refers to being affirmed in one's gender identity or expression. For transgender women, gender affirmation is multidimensional (see **Figure 5**) and may include: social (names, pronouns), psychological (internal felt sense of gender), medical (hormones, surgeries), and legal (legal name change, gender marker change) affirmation. Gender-affirming practices in research and clinical care are also part of facilitating gender affirmation for participants.

Figure 4. Maslow's Hierarchy of Needs

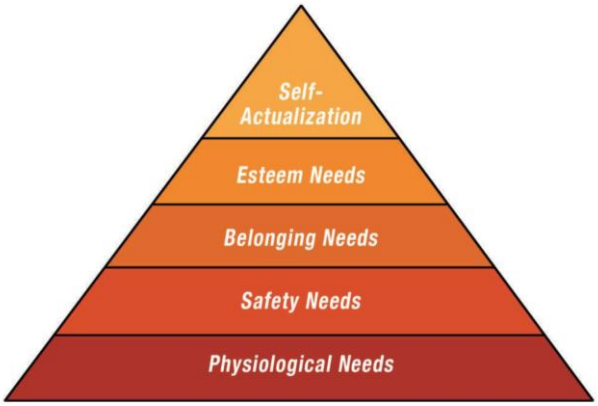


Figure 5. Gender Affirmation

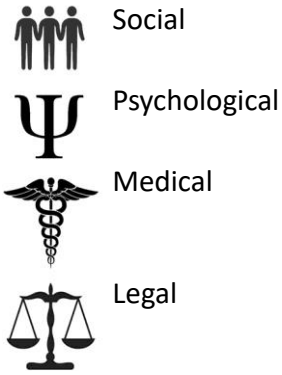


Image from Reisner, Radix, Deutsch, JAIDS, 2016

Gender affirmation and PHN are hypothesized to meet the needs of transgender women for gender affirmation, thereby facilitating transgender women to address other health issues, such as HIV prevention. Thus, gender affirmation is hypothesized to be a pivotal factor in engagement in HIV prevention, including PrEP. Consistent with traditional case management approaches, the PHN intervention will help transgender women navigate removal of systematic and individual barriers to meet needs and therefore to promote health. In addition, the PHN intervention will implement an assets-based approach to identify participant strengths and resiliencies and pragmatically leverage these to promote improved biomedical HIV prevention outcomes.

Strengths-Based Case Management (SBCM)

SBMC is a peer-based intervention that identifies the unique strengths of individuals to help link and navigate them to gender-affirming health and social services. A strengths-based approach combines a focus on the individual's strengths in conjunction with promoting the use of informal community support networks, offering the active community engagement and involvement by the PHN, and emphasizing the relationship between the participant and the PHN.

Six principles characterize the SBCM approach. The SBM method:

- Focuses on a person's strengths and assets, rather than pathology or deficits
- Believes that people, regardless of their current situation or condition, can learn, grow, and change
- Views people as resourceful and resilient when they are in adverse conditions
- Views the community as an oasis of resources and promotes the use of community support networks
- Works with people to self-determine their need for navigation and linkage to gender-affirming health and social services
- Emphasizes the peer-to-peer relationship (together we can) (e.g., a collaborative effort to work "with" peers to achieve their goals)

In HPTN 091, the PHN will help participants identify their unique strengths and overcome their barriers to obtaining and navigating linkages to needed services. The types of services each participant needs, the strengths they bring, the barriers they might experience, and their priorities (in the case of several presenting needs) will vary from participant to participant. The PHN should work with each person to help them identify their strengths and area of greatest need; develop an action plan to meet those needs; and help build the necessary skills so the participant can continue to address their own needs in the future.

Navigation and Linkages

Each site will develop and maintain up-to-date resource lists that include gender-affirming linkages (e.g., housing, legal services, and other health). This will ensure that PHNs are equipped to provide necessary navigation and linkages. Linkages provided by the PHN should be gender-affirming and "vetted" by the site to ensure referrals are culturally responsive and trans-friendly. The PHN will track contacts with participants and contents of interactions.

Healthy Divas + SBCM

Healthy Divas is a peer counseling intervention designed "by" and "for" transgender women that promotes positive change and enhances gender affirmation. The intervention was developed by Dr. Jae Sevelius and a community team at UCSF to improve healthcare engagement.

For HPTN 091, the intervention has been adapted to incorporate SBCM and focus on PrEP uptake and adherence. The 6 sessions are displayed in **Table 2**.

Each PHN session integrates goal setting, assessment and planning tools, linkage and navigation to services (e.g., social, legal, mental health), skills-building activities to empower participants, exercises to affirm participants in their gender identity, and provision of information and educational resources as needed.

Table 2. Overview of 6 Sessions in PHN Intervention

Session #	Session Title	Session Content
Session 1	Let's Be Real!	Introduction, Healthcare in Context, and Gender Affirmation
Session 2	Be Fierce!	Personal Strengths and Resiliency
Session 3	Get it?	Communication and Respect
Session 4	Keeping It Together!	Utilizing Support
Session 5	Work It Out!	Celebrating Successes and Working Through Challenges
Session 6	Healthy Diva!	Envisioning the Future

Each of the 6 PHN intervention sessions is outlined below, including the Tools/Worksheets needed for that session.

Session 1: Let's Be Real! Introduction, Healthcare in Context, and Gender Affirmation

1. Overview of Intervention and Frameworks and Build Rapport and Trust
2. Healthcare in Context
3. Envisioning the: Personal Healthcare Vision
4. Set a Healthcare-Related Goal
5. Discuss Steps to Goal Setting
6. Identify Referral and Navigation Needs
7. Enhance Gender Affirmation
8. Wrap-Up

Tools/Worksheets:

- Healthcare in Context Form
- Envisioning the Future: Personal Healthcare Vision
- Goal Setting Worksheet
- Goal Tracking Worksheet
- Referral and Navigation Sheet
- Gender Affirmation Activity

Session 2: Be Fierce! Personal Strengths and Resiliency

1. Check-In
2. Progress Toward Goal
3. Identify Personal Strengths and Motivators
4. Link Strengths and Motivators to Goals
5. Set a Healthcare-Related Goal

6. Identify Referral and Navigation Needs
7. Enhance Gender Affirmation
8. Wrap-Up

Tools/Worksheets:

- Strengths and Motivators Worksheet
- Strengths-Finder Worksheet
- Goal Setting Sheet
- Goals Tracking Sheet
- Referral and Navigation Sheet
- Gender Affirmation Activity

Session 3: Get it? Communication and Respect

1. Check-In
2. Progress Toward Goal
3. Communication Assessment
4. Communication Practice (Role-Play)
5. Problem-Solving Barriers to Effective Communication
6. Set a Healthcare-Related Goal
7. Identify Referral and Navigation Needs
8. Enhance Gender Affirmation
9. Wrap-Up

Tools/Worksheets:

- Assertive Communication Worksheet
- Active Listening Worksheet
- Goal Setting Sheet
- Goal Tracking Sheet
- Referral and Navigation Sheet
- Gender Affirmation Activity

Session 4: Keeping It Together! Utilizing Support

1. Check-In
2. Progress Toward Goal
3. Review Personal Healthcare Plan
4. Assess Current Support, Learn Types of Support, Identify Barriers and Facilitators to Support
5. Set a Healthcare-Related Goal
6. Identify Referral and Navigation Needs
7. Enhance Gender Affirmation
8. Wrap-Up

Tools/Worksheets:

- Envisioning the Future: Personal Healthcare Vision
- Social Support Worksheet
- Problem-Solving Social Support Worksheet
- Health and Support Worksheet
- Goal Setting Sheet
- Goal Tracking Sheet
- Referral and Navigation Sheet
- Gender Affirmation Activity

Session 5: Work It Out! Celebrating Successes and Working Through Challenges

1. Check-In
2. Progress Toward Goal
3. Review Envisioning the Future: Personal Healthcare Vision
4. Successes
5. Challenges
6. Set Health-Related Goal
7. Identify Referral and Navigation Needs
8. Enhance Gender Affirmation
9. Wrap-Up

Tools/Worksheets:

- Envisioning the Future: Personal Healthcare Vision
- Celebrate Successes
- Trouble-shoot Challenges
- Goal Setting Sheet
- Goal Tracking Sheet
- Referral and Navigation Sheet
- Gender Affirmation Activity

Session 6: Healthy Diva! Envisioning the Future

1. Check-In
2. Progress Toward Goal
3. Review Envisioning the Future: Personal Healthcare Vision
4. Review Skills Learned, Topics in the Intervention, Help Identify How Skills Were Used
5. Set Goals in Healthcare Plan
6. Identify Referral and Navigation Needs
7. Enhance Gender Affirmation
8. Wrap-Up

Tools/Worksheets:

- Envisioning the Future: Personal Healthcare Vision
- Goal Setting Sheet

- Goal Tracking Sheet
- Referral and Navigation Sheet
- Gender Affirmation Activity

PHN Role

The role of the PHN is distinct: to deliver the PHN intervention. The PHN may assist with other site activities, such as recruitment or retention. However, the PHN should not conduct study visits or visit-specific procedures or assessments.

Protecting from Bias

In a randomized controlled trial, contamination refers to the receipt of active intervention among participants in the control arm. Contamination can result in bias and in not being able to detect an intervention effect, even if the intervention if effective. This occurs because the control group begins to "look like" the intervention group.

In HPTN 091, participants randomized to the Immediate Arm receive PHN sessions immediately, whereas those in the Deferred Arm receive the PHN sessions beginning after their 6 mo f/u. Contamination will occur if those in the Deferred Arm begin actively receiving parts of the PHN intervention in the first 6 months.

If both the Immediate and Deferred Arm are receiving active intervention content, this can "wash out" the ability to detect an effect when we compare intervention to control.

Several procedures will protect against bias and ensure the scientific integrity of the study:

- Linkages for the Deferred Arm will not be provided by the PHN in the first 6 months.
    - The PHN may be eager to help all participants immediately. Because this is a research study, it is important that there are delineated roles and that protocols are followed. In some instances, it may feel difficult to defer PHN services, especially when a participant needs those services now. Any linkages provided to participants in the Deferred Arm in the first 6 months should not be provided by the PHN; rather, linkages should be given by study staff and if requested by participants.

- Confidentiality of all PHN sessions is essential.
    - The PHN intervention sessions are delivered in a one-on-one format with the PHN and participant. The PHN should not share anything from the session with their peers, friends, or other participants, nor should the participant. All sessions are confidential and should stay between the PHN and participant. At the beginning of each session, the PHN and participant should explicitly agree that: "What is said here, stays here".

- Session content will not be shared with the Deferred Arm for the first 6 months.
    - The PHN will not be blinded to study arm. PHNs will be provided with a list of people who are in the Immediate Intervention Arm and the Deferred Intervention Arm. This will ensure PHNs know who they are delivering the intervention to currently, as well as to know who not to share the intervention with. It is important not to share the content of the sessions with participants in the Deferred Arm for the first 6 months.

Other Visits/Contact (Outside PHN & Scheduled Clinic Visits)

Participants may contact PHN staff to touch-base or process life situations. These visits should not be included in clinical records and should be added as an addendum to PHN visit records if a situation is directly related to an already discussed issue or a new issue that needs to be addressed during the next PHN session.

If a situation is non-PHN related, please document the contact on separate log for your internal records

Supporting the HPTN 091 Peer Health Navigation Intervention

Three collaborative groups will support delivery of the Peer Health Navigation Intervention: (1) Cross-Site Peer Health Navigator Meeting, (2) Cross-Site Supervisor Meeting, and (3) Site-Specific Case Management Meeting.

Support Type	Description
Cross-Site Peer Health Navigator Meeting (Bi-Monthly)	A cross-site meeting for Peer Health Navigators will be held every 2 weeks. These meetings will be for 1.5 hours. Cross-site meetings will be implemented using a Facilitated Peer Mentoring approach. These meetings are an opportunity for Peer Health Navigators to come together to support one another, get to know one another, and discuss implementation of the intervention, including barriers, facilitators, challenges, and successes. Meetings will help to facilitate meaningful relationships among peers. The group meetings will give Peer Health Navigators the chance to brainstorm and trouble-shoot situations that arise in their work and potential solutions. Meetings will serve to normalize barriers to delivery of the intervention for Peer Health Navigators. The meetings will also help standardize the intervention delivery across sites. Cross-site meetings will be facilitated by the supervisors of Peer Health Navigators from each site. The facilitator of these meetings will rotate to give supervisors at each site the chance to work with Peer Health Navigators from each site, see issues that arise across sites that all Peer Health Navigators are facing, as well as unique challenges that may be occurring at their specific site. The role of the facilitator is not to act as a mentor, but rather to maintain the safety of the group for all participants, to

	ensure that all voices are heard, and to maintain the timekeeping and structure of the meeting. The group meetings are meant to be non-hierarchical, promote peer relationships, encourage reflective practice, build a culture of collaboration, and enhance personal growth and meaningfulness in the work to prevent burnout.
Cross-Site Supervisor Meeting (Monthly)	A cross-site supervisors meeting will be held monthly. These meetings will be for 1 hour. Cross-site supervisor meetings will be implemented using a Facilitated Peer Mentoring approach. These meetings are an opportunity for supervisors to come together to discuss implementation of the intervention, supervision of Peer Health Navigators, and support one another. The group will provide supervisors the opportunity to discuss and brainstorm about challenges, barriers and facilitators, and celebrate successes. The meetings are meant to be collaborative, non-hierarchical, maximize effectiveness of supervisors to supervise Peer Health Navigators, and enhance personal growth and renewal to prevent burnout.
Site-Specific Case Supervision Meeting (Weekly)	Site-specific Case Supervision Meetings will be held weekly with Peer Health Navigators. Supervisors will meet with Peer Health Navigators at their sites to review the sessions, including Goal Setting, Goal Tracking, and Referral and Navigation Sheets for each participant. Supervisors will work with Peer Health Navigators to support them, trouble-shoot barriers that arise, celebrate successes, and ensure intervention fidelity.

Implementation

Any issues, questions, or concerns about implementation of the PHN Intervention should be directed to the site PI, and then to 091PHN@hptn.org.