

Together Learning Choices

A small-group intervention
with young people living with HIV/AIDS

Technical Assistance Guide

The University of California, Los Angeles
Center for Community Health
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SECTION 1: How to Use This Guide

This Technical Assistance (TA) Guide was developed as a resource to provide practical tips and solutions to agencies that are implementing **TLC: Together Learning Choices** (formerly Teens linked to Care), an intervention with young people with HIV.

This TA Guide reviews key information about **TLC**, such as the intervention's core elements and theoretical framework. It addresses common questions about planning and serves as a troubleshooting tool to agencies as they move forward with the implementation of **TLC**.

1.1 Intended Audience for the TA Guide

This guide is intended as a tool for technical assistance providers to help them respond to specific questions from implementing agencies, or as a guide in providing a proactive assessment of and response to an agency's overall TA needs. This guide is intended for:

- CDC-funded Capacity Building Assistance (CBA) agencies that provide technical assistance for **TLC**.
- State and local health departments overseeing delivery of **TLC**.
- Community based organizations implementing **TLC**.
- Facilitators and program staff delivering **TLC**.

Although this guide is geared toward TA providers, it can also be a valuable resource for implementing agencies during the planning and implementing process. The content of this guide was developed from the experiences of two agencies that tested the implementation package, and questions that were raised during Facilitator trainings. Agencies implementing the intervention may use this guide to supplement information provided in the **TLC Implementation Manual** and in **TLC** training materials. It should be noted that this guide is most effective when combined with the assistance of TA providers.

1.2 Content

This TA Guide is comprised of nine sections that are outlined below.

- Section 1: Introduction to the **TLC Implementation Manual**.
- Section 2: List of the **TLC** Intervention Package contents.
- Section 3: Description of **TLC**'s theoretical foundation.
- Section 4: Description of **TLC**'s goals and objectives, core elements, key characteristics, commonly asked questions, appropriate target population, risk factors, and a checklist to help agencies determine the appropriateness of **TLC** for their setting and population.

1.2 Content - *continued*

- Section 5: Discussion of practical matters associated with planning the implementation of the intervention.
- Section 6: Information on costs and resources needed to implement **TLC**. A sample budget is included.
- Section 7: Answers to commonly asked questions about the implementation of **TLC**.
- Section 8: Discussion of ways to tailor **TLC** for an agency's specific population and needs.
- Section 9: Overview of types of evaluation for intervention, including descriptions of formative evaluation, process evaluation, and outcome monitoring.
- Appendices: The appendices in this guide include articles on original research, which cover the background on the intervention, its theoretical premise and the research results; a Stakeholder's checklist; CDC guidelines; suggestions for handling problem behaviors; and sample monitoring and evaluation forms.



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SECTION 2: TLC Intervention Package

The following describes the contents of the **TLC** Intervention Package that will enable agencies to implement this intervention within their own communities.

1. Three-Part *TLC Implementation Manual*

▪ *TLC Implementation Manual, Part 1: Introduction and Overview*

- A brief overview of the intervention, the science behind it, its core elements, and its key characteristics.
- A discussion of capacity issues related to implementing agencies, including a stakeholder's checklist and a budget with cost sheet.
- Guidelines on implementing the intervention.
- Information on evaluating the intervention including an evaluation plan, process and outcome monitoring methods, and sample instruments.
- Several appendices with helpful implementation materials and CDC guidelines.

▪ *TLC Implementation Manual, Part 2: Staying Healthy Module*

- An overview of the *Staying Healthy* module and the science behind it.
- Session guides and Facilitators' notes.

▪ *TLC Implementation Manual, Part 3: Acting Safe Module*

- An overview of the *Acting Safe* module and the science behind it.
- Session guides and Facilitators' notes.

2. Implementation Materials

3. **TLC** Implementation Plan

4. **TLC** Marketing DVD



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SECTION 3: Science-Based Interventions

3.1 Theoretical Concept

The **TLC** intervention is based on Social Action Theory (See Appendix F). Social Action Theory asserts that a person's ability to change behaviors that endanger his or her health is influenced by the individual's cognitive capability (ability to think, reason, imagine, etc.) as well as environmental factors and social interactions that encourage or discourage the change process. Social Action Theory incorporates the principles that are expressed in traditional social-cognitive models of health-behavior change. These models include social-cognitive theory, the health belief model, and the transtheoretical model (stages of change), as well as theories related to social context, interpersonal relationships, and environmental influences.

Social Action Theory considers that behaviors, environment, attitudes, and beliefs influence and depend on each other. Therefore, in order for persons to successfully change their behavior, they need:

- Problem-solving skills to encourage and facilitate individuals to assess and identify potential barriers (internal and environmental) to self-change and develop appropriate strategies to overcome them.
- Positive outcome expectancies, the belief that good things will happen as a result of the new behavior.
- Self-efficacy (i.e., one's belief in their ability to control their own motivations, thoughts, emotions, and specific behaviors, and confidence that he or she can persist in the face of temptation).
- Social interaction skills within interpersonal relationships (e.g., the ability to communicate effectively, to negotiate, and to resist pressures from others) to promote relationship support.
- Self-regulating skills (e.g., the ability to motivate, guide, and encourage oneself and to problem-solve).
- Rewards (reinforcement value) produced by attempts at a new behavior.

According to Social Action Theory, these necessary things can be achieved by:

- Assessing the internal or external barriers to self-change.
- Developing strategies to overcome these barriers.
- Increasing an individual's motivation to change.
- Promoting the expectation that the outcome of the change will be valuable and desirable.
- Appraising the pros and cons of the adopted behavior, highlighting the intrinsic positive aspects of the new behavior, and rewarding the new behavior (incentives).

- Observing other people’s behaviors and experiences (modeling).
- Learning from the experiences of others (gathering information, successful strategies, and shaping outcome expectations).
- Participating in guided practice or rehearsal of new behaviors and skills.
- Receiving corrective feedback and/or praise on one’s performance of a behavior or skill.
- Acquiring personal experience with new behaviors and skills.
- Receiving social support for new behaviors.

Feel-Think-Do

TLC applies the Social Action Theory by emphasizing the awareness and identification of one’s emotions, thoughts, and actions, which we refer to as the Feel-Think-Do Framework (F-T-D). F-T-D is a simple, low-literacy means of introducing more complex cognitive-behavioral concepts (e.g., emotional regulation, reframing, self-talk, problem-solving, assertive behavior and communication, triggers). It describes an interactive process. F-T-D is based on the idea that when we encounter a situation, we have a feeling about it (discomfort expressed through a reading on the Feeling Thermometer that is used throughout the intervention and body reactions), a thought about it (what we say to ourselves), and what we do about it (the actions we take as a result of our feelings and thoughts). **TLC** participants are guided by F-T-D to recognize the connections between their thoughts and feelings and the behavioral choices they make, enabling them to more easily make behavioral changes.

3.2 Commonly Asked Questions

- 3.1.1 What are the concepts of Social Action Theory?
- 3.1.2 What is the Feel-Think-Do Framework and how does it relate to the theory?

3.1.1

Q. What are the concepts of Social Action Theory?

- A. The concepts of Social Action Theory state that in order for persons to successfully change their behavior they need:
 - Problem-solving skills to encourage and facilitate individuals to assess and identify potential barriers (internal and environmental) to self-change and develop appropriate strategies to overcome them.
 - Positive outcome expectancies, the belief that good things will happen as a result of the new behavior.
 - Self-efficacy (i.e., one’s belief in their ability to control their own motivations, thoughts, emotions, and specific behaviors, and confidence that he or she can persist in the face of temptation).
 - Social interaction skills within interpersonal relationships (e.g., the ability to communicate effectively, to negotiate, and to resist pressures from others) to promote relationship support.

3.2 Commonly Asked Questions - *continued*

- Self-regulating skills (i.e., the ability to motivate, guide, and encourage oneself and to problem-solve).
- Reward (reinforcement value) produced by attempts at a new behavior.

3.1.2

Q. What is the F-T-D Framework and how does it relate to the theory?

- A. **TLC** applies the Social Action Theory by emphasizing the awareness and identification of one's emotions, thoughts, and actions, which we refer to as the Feel-Think-Do Framework (F-T-D). F-T-D is a simple, low-literacy means of introducing more complex cognitive-behavioral concepts (e.g., emotional regulation, reframing, self-talk, problem-solving, assertive behavior and communication, triggers). It describes an interactive process. F-T-D is based on the idea that when we encounter a situation, we have a feeling about it (discomfort expressed through a reading on the Feeling Thermometer that is used throughout the intervention and body reactions), a thought about it (what we say to ourselves), and what we do about it (the actions we take as a result of our feelings and thoughts). **TLC** participants are guided by F-T-D to recognize the connections between their thoughts and feelings and the behavioral choices they make, enabling them to more easily make behavioral changes.



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SECTION 4: Description of TLC: Together Learning Choices

General Overview

TLC: Together Learning Choices is an evidence-based HIV prevention and health promotion intervention with young people (ages 13 to 29) living with HIV. **TLC** is delivered in small groups using cognitive-behavioral strategies to change behavior. It provides young people with the tools and skills necessary to live their best life and to be able to make healthy choices.

Evidence-based interventions have been tested through rigorous research and have been shown to be effective in reducing risky behaviors, such as unprotected sex, or in encouraging safer ones, such as using condoms and other methods of practicing safer sex.

TLC consists of three sequential modules, each eight sessions in length.

- The *Staying Healthy* module encourages healthy living by focusing on health maintenance and forging effective partnerships with health care providers.
- The *Acting Safe* module is dedicated to primary and secondary HIV prevention by addressing sex- and substance use-related risk behaviors.
- *Being Together* emphasizes emotional well-being and improving quality of life. It is not included in this package, but is offered as an optional module.

Research on the Intervention

TLC was evaluated with 310 HIV-positive youth ages 13 to 24 who were assigned either to an intervention or a comparison condition. Of the youth in the intervention condition, 73% attended at least one session. The detailed results of the research study can be found in the published articles included in the Appendices.

Following the *Staying Healthy* module, the number of positive lifestyle changes increased 45% and use of positive coping styles increased 18% among females in the intervention compared to females in the comparison condition. Seeking and obtaining social support increased 11% among both genders in the intervention as compared to those in the comparison condition. All these changes were statistically significant.

Following the *Acting Safe* module, intervention participants reported 82% fewer unprotected sex acts, 45% fewer sex partners, 50% fewer HIV-negative sex partners, and 31% less substance use than those in the comparison condition. Again, all of these changes were statically significant.

Modifications to the Intervention

During its preparation for use in the field, **TLC** was adjusted in the following ways to make implementation easier.

Materials for the *Being Together* module are not included as part of this intervention package. The module was not rigorously evaluated due to limited follow-up data and the outcomes were not linked to HIV risk reduction. However, the *Being Together* module significantly lowered overall emotional distress, expressions of emotional distress through physical symptoms, and anxiety scores among youth in the intervention compared to youth in the comparison condition. In addition, youth in the intervention reported significantly less frequent use of nondisclosure as a coping mechanism than did youth in the comparison condition. The techniques used in this module may require extended training. For these reasons, *Being Together* is offered as an optional module. Materials, training and technical assistance for implementation may be obtained from the UCLA Center for Community Health, or the full module may be accessed at <http://chipts.ucla.edu>.

TLC was originally called Teens Linked to Care because it was designed to target teens and youth (ages 13 to 24) enrolled in HIV treatment programs. The intervention was renamed **TLC: Together Learning Choices** to better reflect the intervention's goals of linking HIV-positive young people to a broad range of care that includes emotional and social support as well as medical treatment.

TLC has been expanded to target HIV-positive young people from a wider age range (ages 13 to 29) who are receiving HIV-related services in a wider range of settings that include both medical clinics and social service agencies. The intervention addresses challenges faced by both HIV-positive adolescents and young adults and can be easily be adapted to a variety of settings, such as mental health centers.

It was also necessary to reduce the *Staying Healthy* and *Acting Safe* modules to eight sessions each, instead of the eight-to-twelve sessions that were originally offered. The Community Advisory Board that consulted with the **TLC** replication team strongly recommended a smaller number of sessions to make it feasible for agencies to implement the intervention and to successfully retain participants. This decision is consistent with the original research on **TLC** in which the mean number of sessions participants attended was 7.7 for *Staying Healthy* and 7.6 for *Acting Safe*. Seventy percent of participants attended at least six sessions of *Staying Healthy*, while 73% attended at least five sessions of *Acting Safe*. This decrease in number of sessions did not result in reduction or change to the content of the intervention. Other changes that were made to the original protocol include:

- Elimination of redundant concepts and activities.
- Addition of updated information on prevention technology, medical management of HIV, and common “club drugs”.
- Integration of a perspective that treats HIV as a chronic disease.
- Greater emphasis on non-scripted role plays.
- Incorporation of a Feel-Think-Do Framework that more explicitly highlights the intervention's underlying theory and the link between feeling, thought, and action.

4.1 Goals of TLC

The overall goal of **TLC** is increasing behaviors that promote:

- Healthy living.
- Effectively dealing with the challenges of daily living.
- Positive feelings, thoughts, and actions.
- Developing daily routines to stay healthy.

The *Staying Healthy* module supports the overall goal of **TLC** by:

- Increasing positive health related behaviors.
- Increasing positive coping skills for a healthy future and for managing challenges associated with stigma.
- Improving communication skills for positive relationships with health care providers.
- Decreasing barriers to successful medication adherence.

The *Acting Safe* module supports the overall goal of **TLC** by:

- Reducing the number of unprotected sex acts.
- Reducing the number of sex partners.
- Decreasing the number of uninfected sex partners or partners of unknown status.
- Reducing risky drug use behaviors.

These goals are achieved through **TLC**'s core elements (see discussion of core elements in Section 4.2). During the sessions the participants see behaviors modeled, practice those skills, and as a result of skill acquisitions, are able to make the necessary behavioral changes.

4.2 Core Elements and Key Characteristics of TLC

Core Elements of TLC

Core elements are critical features of an intervention's intent and design and are responsible for its effectiveness. They must be maintained without alteration.

The following are core elements of **TLC**.

1. Development of emotional awareness through use of a Feeling Thermometer and identification of the link between feelings, thoughts, and actions (F-T-D Framework).
2. Teaching, modeling and practicing four **TLC** essential skills:
 - a. Personal Problem-Solving.
 - b. Short- and Long-Term Goal Setting.

- c. Emotional Awareness and Regulation.
- d. Assertive Behavior and Communication.
3. Consistent appreciation and reinforcement of positive participant behavior through the use of Thanks Tokens.
4. Identification of Ideal Self to help motivate and personalize behavior change.
5. Sessions delivered in small, highly participatory, interactive groups.

Through **TLC's** core elements, participants develop specific skills that give them a sense of control over their emotions and subsequent thoughts and actions. These skills are repeated and modeled in every session to provide participants with opportunities to practice the skills and ultimately apply them in everyday situations.

Key Characteristics of TLC

The following key characteristics are crucial activities and delivery methods for conducting **TLC**, however they may be tailored to meet the needs of different agencies and at-risk populations. Key characteristics of **TLC** include:

- **Use of incentives.** We recommend using incentives to encourage participants to return to sessions, but it is up to each implementing agency to decide whether or not to use incentives, what kind to use, and the estimated value of an incentive. The most appropriate incentive strategies are those that your community advisory group and your participant pool think will work best to encourage attendance and participation.
- **Time.** With practice, all sessions can be finished in the two-hour time period indicated in the ***TLC Implementation Manual***. Although the agencies that tested the **TLC** Intervention Package ended up extending the length of their sessions as a result of discussions running longer, it is recommended that the sessions be kept to two hours as much as possible.
- **Intervals between sessions** can be tailored to the needs and capacity of your agency and population. A general rule of thumb is to conduct sessions once a week. Biweekly also may work for you, but we do not recommend monthly sessions except in very unusual situations. Facilitators want to allow participants enough time to practice the skills learned in the group and make progress on their goals, but not so much time that they forget lessons or lose interest. When planning for the session frequency, there are several things to be considered:
 - Time for participants to think about what they have experienced.
 - Ability to retain participants.
 - Availability of both participants and Facilitators.

It is not recommended that an agency conduct all eight sessions in one day or a weekend.

Key Characteristics of TLC - *continued*

- **Facilitators.** Two Facilitators are needed to run the groups. The same two Facilitators will be able to enhance group cohesiveness much better than having different Facilitators for different sessions. While it is preferable to have one Facilitator be male and one female (for purposes of modeling and providing a gender-specific point of view to the participants), that may not be possible in every circumstance, so when necessary, same-gender Facilitators can conduct the sessions. If your group is all of one gender (all male, for instance), one of the Facilitators should be of this gender.
- **Group composition.** Implementing agencies may modify **TLC** with respect to the age, gender, and sexual orientation of participants. For example, if your agency’s potential participant population is sufficiently large, you may wish to consider holding separate groups for younger (e.g., under 18) and older participants. You may not change **TLC** from a group to an individual delivery method, but the composition of the group is flexible. Contact the UCLA Center for Community Health about similar interventions that are effective for individual use.
- **Group size.** We recommend that **TLC** groups be from 4 to 8 participants in size, though slightly larger groups (up to 12) may be workable once your Facilitators have sufficient experience with the intervention to be comfortable with a larger group.
- **Building group cohesion.** Building cohesion is essential to **TLC** because participants may disclose personal experiences and they need to feel safe and supported as they do so. Building cohesion lays the foundation for building trust, and trust creates the safe and supportive environment necessary for **TLC**. The agencies that tested the intervention used a variety of cohesion building activities. Some agencies used introductory sessions; others used meals served before or after the sessions. Other ways to build group cohesion are using “energizers” or “getting to know you” activities before, during or after the sessions.
- **Food/snacks.** Implementing agencies are encouraged to provide refreshments for their participants. This is not a core element but strongly recommended.
- **Visual aids.** The use of visual aids like the wall charts supplied in the **TLC** Intervention Package can help in the comprehension and retention of concepts. Visual aids can also help participants who have low literacy skills. It is recommended that visual aids be simple and universally understood.
- **Location.** **TLC** can be held anywhere there is a private room with enough space to accommodate the participants, the role plays and a refreshment table. The venue and room should be accessible to the handicapped. For some communities, venues that advertise services for people living with HIV/AIDS are not good places to hold **TLC** sessions. Since some participants may not have disclosed their status and therefore would not attend sessions at a place that might compromise their privacy.

4.3 TLC Essential Skills and TLC Learning Techniques

The intervention uses teaching, modeling, and practicing of four **TLC** essential skills:

1. Personal Problem-Solving.
2. Short- and Long-Term Goal Setting.
3. Emotional Awareness and Regulation.
4. Assertive Behavior and Communication.

Personal problem-solving skills are presented using a structured model called SMART, which involves five steps: 1. State the problem, 2. Make a goal, 3. Achieve a list of all possible actions, 4. Reach a decision, 5. Try it and review it. Through this model, participants learn to analyze and identify different actions they might take toward solving a real-life problem. Participants are invited to bring up general problems to which they may be seeking solutions, or a difficult problem related to one of the sessions. The group applies the problem-solving format, selects a goal, identifies barriers, and plans the next steps. This newly learned life skill can be applied to a broad range of problems within and outside the context of HIV prevention.

Short- and long-term goal setting occurs during the conclusion of sessions and usually focuses on a goal related to that sessions' activities or topic. Participants are taught the characteristics of good goals—realistic, clear, challenging but not impossible, and having an identifiable end-point. Once participants choose a goal, they identify the steps they will take before the next session to achieve that goal. A check-in period occurs in the first few minutes of the following weeks' session to discuss what happened. Not only is there the intrinsic reward of achieving one's goal (for those who do), but Facilitators reward (with praise and Thanks Tokens) the attempts that have been made. For those participants who did not achieve their goals, the check-in period allows them to analyze the reasons they were not successful.

Emotional awareness and regulation is another central element of TLC. When young people are not able to identify their feelings accurately they are less able to deal with those feelings effectively. Many young people, for instance, describe feeling angry when they are, in fact, hurt and so their responses are likely to be more on the order of lashing out than acknowledging pain or hurt feelings and negotiating a solution to what has caused the hurt. TLC teaches participants how their thoughts, feelings and actions influence each other. This awareness and techniques learned in TLC sessions help participants deal with their emotions and replace negative thoughts with positive thoughts, which leads to more positive and effective actions.

Assertive behavior and communication are vital for effective and successful interactions with others. Verbal and non-verbal assertiveness facilitates the implementation of the skills taught in this intervention. For example, as a part of the choices we all have, we can choose to be passive, assertive, or aggressive. Participants are introduced to verbal and non-verbal assertiveness surrounding various life contexts (i.e., condom negotiation, interactions with health care providers, family members, etc.). Role plays are often utilized to provide participants with the opportunity to practice assertiveness. Facilitators repeatedly tie in verbal and non-verbal assertiveness skills with various session topics and model assertiveness skills whenever the opportunity arises.

4.3 TLC Essential Skills and TLC Learning Techniques - *continued*

The intervention uses the following four **TLC Learning Techniques**:

1. The Feeling Thermometer.
2. Thanks Tokens.
3. Identification of the Ideal Self.
4. Role Plays.

The Feeling Thermometer is displayed on the wall during every session and helps participants assess and discuss their feelings of discomfort more effectively during the session. The Feeling Thermometer is a graphic design resembling a fever thermometer that has been enlarged and reproduced on a poster. The highest measurement on the Feeling Thermometer is 100 and it represents the most discomfort one can imagine feeling. That discomfort may be extreme anger, anxiety, excitement, nervousness, depression or any other emotion that is experienced as discomfort. The bottom measurement is zero and this represents a total lack of discomfort, whether the associated feeling is happiness or calm or something else.



Linking Feeling Thermometer levels with situations being discussed or with recent experiences helps participants identify when their emotions are or have been highly charged and what situations are likely to result in those high extremes of feelings. The person at or near 100 on the thermometer is likely to find that his or her discomfort interferes with good judgment and sound decision-making. The person at or near zero on the thermometer is better able to think and make decisions regardless of how he or she labels the particular feeling or emotion. The purpose of the Feeling Thermometer is to increase participants' emotional awareness and self-regulation.

Thanks Tokens are two-inch-square pieces of laminated cardstock with a design on one side (a star is used in **TLC**, but another design may be substituted if you prefer). When praising a participant for a meaningful contribution to the session, such as for speaking out on an issue or coming up with an idea, the Facilitator will accompany the praise with a Thanks Token. The intent is to pair a compliment with a tangible symbol of appreciation to draw the participant's attention to the fact that he or she has been complimented. The Facilitator explains why the Thanks Token was given, e.g., "I liked your suggestion of how we might explain that better," or "I appreciate how you spoke up on that," at the time it is handed to the participant.



Each participant is also handed a packet of 20 Thanks Tokens at the beginning of each session. Participants are asked to give a Thanks Token, along with a brief description of why, whenever another participant says or does anything he or she appreciates. In this manner, participants learn to deliver as well as receive compliments. When used consistently by both Facilitators and participants, Thanks Tokens leave most participants with positive feelings about themselves. It is important to note that Thanks Tokens are not a medium of exchange and are not "turned in" for anything of value. (Actually, participants will be asked to return the tokens at the end of the session so they can be reused in the next session.)

The key to everyone using the Thanks Tokens rests on the Facilitators' comfort with them. If the Facilitators like using them and do so at every opportunity, the participants will also use them. **TLC** has been designed so that Thanks Tokens are designated to be used multiple times in every session. However, Facilitators are also encouraged to use Thanks Tokens whenever any other opportunities to use them arise in a session.

Both the Feeling Thermometer and Thanks Tokens are also used in **Street Smart**, another evidence-based intervention available from CDC's Prevention Research Branch-Replicating Effective Programs. The same techniques are used in both interventions; however, their explanations in this manual are more detailed and reflect insight gained from field-testing the **TLC** intervention.

Identification of Ideal Selves helps **TLC** participants pinpoint their values as they relate to the way they would like to see themselves behave. Participants are asked to consider those values as they think about the ways they would like to act in specific situations. The Ideal Self is used as a decision-making guide to help motivate and personalize behavior change. Appeals to one's Ideal Self occur throughout the sessions.

Role plays allow participants to watch and/or practice positive responses to potentially problematic situations in an instructive and supportive environment. The **TLC** manual contains different types of role plays. A few are scripted and are used to introduce a particular session or topic. These scripted role plays should be practiced ahead of time and are to be acted by Facilitators, not participants. Other role plays are not scripted but a scenario is described and participants are asked to act it out without preparation. These role plays give participants an opportunity to explore new ways of dealing with high-risk situations. Instructions for each role play are found within the session guides. Facilitators should not let a role play go beyond 10 minutes and should monitor it to assure that participants understand and keeping to the point.



It is important to make every effort to avoid role playing of stereotypes. Many of the role play situations describe interactions between persons with specific characteristics. These role plays are not intended to stereotype individuals by gender, age or race—in fact, the Facilitators are encouraged to reverse stereotype roles whenever possible. For example, have a female play the role of the person who does not want to use a condom, or have young men role play young women and women role play men. This gives participants an opportunity to explore others' experiences and points of view.

4.4 Format of Sessions

TLC's modules are delivered in highly interactive small groups. Exercises in each session are developed to create meaningful personal experiences, leading to increased skills and development of the attitudes and knowledge needed to support the acquisition of new behaviors.

A small group of 4 to 12 young adults (ages 13 to 29) meets regularly to provide social support, learn and practice new skills, and to have fun together. Once a module begins these small groups are closed to new members. Groups can be mixed gender. Participants sit in a circle and share common experiences throughout eight 2-hour sessions. Two Facilitators lead participants through the **TLC** content.

TLC leads participants to explore the pros and cons associated with behavior change in the context of disclosure, safer sex practices, maintaining health, and improving the quality of their lives. Participants observe others, share experiences, practice new skills, and receive feedback from other group members. The group experience can have powerful effects on individual behavior, challenge perceptions that promote risk, and shift attitudes to support prevention. At the beginning of each session, participants review their progress toward achieving goals and regular positive reinforcement is used in the intervention. In the middle of each session, Facilitators focus participants on skill development, attitude formulation, knowledge acquisition, and/or reframing of previous dysfunction behavior patterns. **TLC** participants practice new skills and behavior using role plays.

4.5 TLC's Intended Target Populations

TLC is an appropriate intervention for young people (ages 13 to 29) living with HIV.

4.6 Determining Whether to Implement TLC

Before implementing **TLC**, decision makers should assess their organization's readiness and capacity to implement this evidence-based HIV prevention intervention. The purpose of this checklist is to stimulate thinking and engage key decision makers in a dialogue, so they might ask each other the right questions to determine if they wish to implement **TLC**. The checklist also provides questions agencies need to explore when thinking about adapting the intervention. This checklist is not exhaustive.

- What is your agency's philosophy of prevention? What are the values, attitudes, and beliefs of your staff about prevention? What is your staff's commitment to prevention services for individuals who are living with HIV/AIDS?
- What is your agency's past experience in implementing interventions like **TLC** with the HIV-positive community?
- Does **TLC** advance the mission of your agency?
- How does **TLC** fit into your current prevention services?
- Are the **TLC** risk reduction messages appropriate for your organizational norms and values?
- Is your target population among those for whom **TLC** was demonstrated to be effective?
- Does your target population need an intervention that deals with prevention and health promotion?
- Would **TLC** serve the needs of your target population?
- Does **TLC** address the factors that put individuals in your target population at risk?
- Are **TLC**'s goals appropriate for your target population?
- Does your organization have the staffing capacity to implement each of the **TLC** sessions?
- Do you have the capacity to recruit members of the target population for the **TLC** intervention?
- Does your agency have adequate space to implement **TLC**?
- What policies will need to be developed to implement **TLC**?
- What types of organizational changes will need to occur to ensure that **TLC** is implemented successfully?
- Will implementing **TLC** change your agency's relationship with other prevention and/or services agencies?
- Can your organization successfully adapt **TLC** to meet its needs and that of its target population?

4.7 Commonly Asked Questions

- 4.0.1 What does **TLC** stand for?
- 4.0.2 What are “evidence-based” interventions?
- 4.0.3 With whom, when, and where was the original intervention tested?
- 4.0.4 What were the results of the original research project?
- 4.0.5 What is an appropriate age of participants in **TLC**?
- 4.0.6 Is it appropriate for younger participants (e.g., age 13) to be in a group with older young people (e.g., age 24)?
- 4.0.7 What if the group is composed of participants with diverse functioning levels and life-coping skills?
- 4.0.8 Is it OK to have group members with different sexual orientations in the same group?
- 4.2.1 What are the core elements of an intervention?
- 4.2.2 What are the core elements of **TLC**?
- 4.2.3 What are the key characteristics of an intervention?
- 4.2.4 What are the key characteristics of **TLC**?
- 4.4.1 What happens in a **TLC** group session?
- 4.6.1 What types of agencies have implemented **TLC**?

4.0.1

*Q. What does **TLC** stand for?*

A. **TLC: Together Learning Choices** is an effective HIV prevention and health promotion intervention for young people (ages 13 to 29) living with HIV. It is delivered in small groups using cognitive-behavioral strategies to change behavior.

See Sections 4.1-3 for more details.

4.0.2

Q. What are “evidenced-based” interventions?

A. Evidence-based interventions are interventions that have been tested through rigorous research and have been shown to be effective.

TLC and other interventions that are part of CDC’s Replicating Effective Programs are evidence-based interventions.

4.7 Commonly Asked Questions - *continued*

4.0.3

Q. With whom, when, and where was the original intervention tested?

- A. **TLC** was first conducted in 1994-96. The intervention was conducted as a multi-site trial administered to high risk youth populations in clinical settings in Los Angeles, Miami, San Francisco, and New York. **TLC** originally was implemented with young people living with HIV/AIDS ages 13 to 24, most of whom were youth of color.

The intervention's success with this population, the subsequent increase in young adults in their later 20s who are living with HIV, and the lack of evidence-based interventions for this population suggested the need for **TLC** to be extended to a slightly broader age group. The agencies who tested this intervention package recruited HIV-infected young adults ages 13 to 29, the current age for **TLC**'s target population, to participate.

4.0.4

Q. What were the results of the original research?

- A. The intervention was evaluated with 310 HIV-positive youth assigned to either the intervention or a comparison condition.

See the General Introduction to Section 4 where the results of the original research are discussed.

4.0.5

Q. What is an appropriate age of participants for TLC?

- A. **TLC** is appropriate for teens and young adults. The agencies that tested the **TLC** Intervention Package had participants ranging from 13 to 29 years of age, with an average age of 21.

4.0.6

Q. Is it appropriate for younger participants (e.g., age 13) to be in a group with older youth (e.g., age 24)?

- A. In our experience, older youth are often supportive and serve as mentors for younger youth in a group. Facilitators are also trained in teaching youth how to apply concepts that they may not have personally experienced. For example, if some youth do not engage in drug use at all, an alternative in this section of the intervention would be to substitute food, cigarettes, or some other habit that can lead to unhealthy behaviors. Additionally, youth may choose to focus on just maintaining their current abstinence. However, if there are enough interested participants, Facilitators may want to consider starting two groups with youth similar in age.

4.0.7

Q. What if the group is composed of participants with diverse functioning levels and life-coping skills?

- A. **TLC** has proven to be effective when participants come from high levels of functioning (e.g., working, in school, in a relationship, etc.) and also with participants whose social

functioning is more challenged (e.g., homeless, injection drug users, unemployed, etc.) **TLC** is carefully designed to benefit young people at all levels of functioning. Agencies implementing **TLC** may use their discretion to decide if they prefer to create two groups that are more similar or to allow the group to remain open to all interested participants.

4.0.8

Q. Is it OK to have group members with different sexual orientations in the same group?

A. Yes. Agencies that participated in the pilot testing of **TLC** reported that diverse groups (both in terms of gender and sexual orientation) resulted in strong group cohesion as participants problem-solve together.

4.2.1

Q. What are the core elements of an intervention?

A. Core elements are critical features of an intervention's intent and design. They are thought to be responsible for an intervention's effectiveness and put an intervention's underlying theoretical constructs into operation. Accordingly, core elements must be maintained without alteration to ensure the effectiveness of the program.

See Section 4.2 where core elements are described.

4.2.2

Q. What are the core elements of TLC?

A. There are five core elements of **TLC**.

See Section 4.2 where the core elements of **TLC** are described.

4.2.3

Q. What are the key characteristics of an intervention?

A. Key characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations and to ensure cultural appropriateness.

See Section 4.2 where the key characteristics of **TLC** are described.

4.2.4

Q. What are the key characteristics of TLC?

A. The key characteristics of **TLC** include: use of incentives, intervals between sessions, time, session frequency, Facilitators, group composition, group size, building group cohesion, use of food or snacks, visual aids, and location.

See Section 4.2 where the key characteristics of **TLC** are described.

4.7 Commonly Asked Questions - *continued*

4.4.1

Q. What happens in a TLC group session?

A. **TLC's** modules are delivered in highly interactive small groups. Exercises in each session are designed to create meaningful personal experiences, leading to increased skills and development of the attitudes and knowledge needed to support the acquisition of new behaviors.

- Sessions begin by reviewing participants' previous goals.
- Facilitators provide fun and engaging activities focused on: problem-solving, attitude formulation, knowledge acquisition, and/or skill development.
- Facilitators help participants to reframe negative behavior patterns.
- Facilitators reinforce desired behavior through the use of incentives (Thanks Tokens).
- Participants set a new goal.

See Section 4.4 for more details.

4.6.1

Q. What types of agencies have implemented TLC?

A. Many different types of agencies have used **TLC**. The agencies involved in **TLC's** development were community based organizations, clinics, substance abuse treatment centers, and AIDS service organizations. These agencies implemented the intervention with existing clients who comprised a diverse mix of young people living with HIV/AIDS, most of whom were people of color.



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SECTION 5: Planning to Implement TLC

This section of the TA Guide will help prepare an agency to deliver **TLC: Together Learning Choices**. Before getting started, agencies must understand how, where, and for whom **TLC** will be implemented, and mobilize the support necessary for successful implementation. Prior to implementation, an agency should learn more about its target population, access needed resources, develop marketing and evaluation plans, and make any necessary organizational changes.

5.1 Pre-Implementation

Successful execution of **TLC** requires the completion of several pre-implementation activities.

Needs Assessment

Conducting a needs assessment that describes the needs of the population and the factors that put them at risk is an important pre-implementation activity. A needs assessment may include one or more of the following activities:

- Identifying and analyzing local epidemiological reports.
- Exploring factors that influence risk behaviors of the target population.
- Examining the local or state comprehensive HIV prevention plan developed in compliance with CDC's HIV Prevention Community Planning Guidance (CPG).
- Consulting with service providers, members of the target population, and other individuals who possess key knowledge through focus groups or structured interviews.

Planning

During **TLC's** pre-implementation phase, agencies work with their staff and members of the target population to identify:

- The feasibility of conducting the intervention given the agency's resources, capabilities, mission, and experience.
- Key stakeholders from whom buy-in will be sought.
- A "champion" to mobilize support for **TLC**.
- Locations for the intervention sessions.
- Plans for evaluation efforts including data collection and analysis.
- Appropriate participant incentives and sources - such as local merchants - for these incentives.

- Appropriate Facilitators and their training needs.
- Opportunities for tailoring the intervention to better fit the target population.
- Strategies and policies to support recruitment and retention.
- Supplies of condoms and lubricant for distribution to participants.
- Local or state laws regarding requirements to disclose HIV status or “duty-to-warn” laws.

It is suggested that agencies wanting to implement **TLC** form a community advisory group. A community advisory group recruited from opinion leaders of the target population can assist with completing the formative evaluation and assist with tailoring **TLC** to meet local needs. (The role of an advisory committee in tailoring **TLC** is discussed in detail in Section 7.)

Buy-In

Securing “buy-in” is crucial because it assures the support of agency administration and facilitates the allocation of agency resources for implementing the intervention. Obtaining buy-in is most effectively accomplished with an intervention champion. A champion is a mid- to upper-level administrator within the agency who serves as the intervention’s spokesperson, anticipates and answers questions about the need for the intervention, and is familiar with the resources needed to implement the intervention. The champion can be an individual or a group of people, but regardless of the number of champions, their central purpose is convincing agency staff and others that implementing **TLC** would enhance the quality of prevention services provided by the agency and that the agency is capable of implementing the intervention. The champion must have excellent knowledge of the intervention including its costs, core elements, and key characteristics. The champion can use the **TLC** Marketing DVD and other information presented in the intervention package to gain the support of stakeholders, and to answer any questions or concerns they might have about **TLC**.

In addition, agencies should obtain “buy-in” from the appropriate local or state HIV prevention planning body developed in compliance with CDC’s HIV Prevention Community Planning Guidance (CPG). Each planning group develops a comprehensive HIV prevention plan for a project area. This plan will help in assessing the need for **TLC** and the role it will play in the local prevention continuum of care.

5.2 Recruitment of Participants

We strongly recommend that agencies develop a recruitment strategy very early in the planning stage. The plan should draw upon ideas and techniques used in the past to recruit and retain participants in programs.

Recruitment plans should target three groups: the staff of the implementing agency; other agencies in the community serving the target population; and members of the target population. It is important to develop talking points for these groups that describe **TLC** as:

- An effective intervention that addresses HIV prevention and the health promotion needs of teens and young adults living with HIV.
- An intervention group that provides the target population the opportunity to meet other young people living with HIV/AIDS in a relaxed, fun atmosphere.

5.2 Recruitment of Participants - *continued*

Each group needs to understand **TLC**'s goals, target population, and attendance expectations. Agencies that implemented **TLC** were able to recruit and retain between eight and 11 participants.

Possible places from which to recruit participants include:

- Referrals from agency staff (e.g., case managers, prevention counseling case managers, mental health counselors, treatment advocates, and clinic staff).
- Support groups.
- Referrals from agencies providing services to persons living with HIV/AIDS.
- Direct contact by outreach or other agency staff.
- Word of mouth from other participants.
- Flyers, brochures, and posting on Internet community bulletin boards.

While recruiting participants, it is important to remember:

- Since **TLC** is a closed group, participants may not drop in occasionally.
- **TLC** is not meant for couples.
- While appropriate for individuals struggling with substance abuse issues, a **TLC** group ground rule is that members not attend it while high or intoxicated.

Pre-session Interviews

Some agencies have conducted pre-session interviews with potential participants. The interview gave Facilitators the opportunity to obtain information about the participant's background and prior group participation. This information assisted in identifying individuals who might not be a good fit for the group. The background information also helped the Facilitators to personalize the session content to the needs of the participants.

5.3 Retention

TLC is a closed group. Once the sessions begin, participants cannot be added to the group. Participants should not miss two consecutive sessions. Each session builds on the previous session. Missing more than one session undermines the participant's ability to fully grasp the skills, making it difficult to participate in the other sessions.

Implementing agencies need to develop attendance policies that support the goals of **TLC** and clearly communicate these to participants and other stakeholders in the intervention.

Ways to increase retention and attendance at **TLC** group sessions can include reminders such as, telephone calls, text messaging group members the day before a session, sending an "e-vite" invitation through e-mail, sending instant message reminders, sending regular e-mail reminders, and even through the postal service by mailing reminder cards each week. Facilitators may want to discuss reminders with the group to find out what form of contact is best.

5.4 Incentives

Incentives are not a requirement for **TLC** but can provide an extra motivation for young people to keep attending **TLC** group sessions. Incentives will vary by agency, based on resources, agency policy, and needs of the specific target group. Incentives may range from cash or gift cards, to a bus token or a key chain. Feeling good about the decision to participate in **TLC** may be an incentive in itself!

Some agencies have been successful in soliciting incentives from local businesses. Seeking in-kind donations helps promote the mission of the agency in the community. It also gives local businesses an opportunity to participate in a larger HIV prevention effort.

5.5 Staffing Patterns

Implementing **TLC** typically requires an implementation team consisting of a Program Manager and two Facilitators. Depending on local financial and human resources, a Program Assistant and trained volunteers also may be directly involved in the activities related to implementing **TLC**.

Major responsibilities of the Program Manager include:

- Maintaining program integrity.
- Ensuring fidelity to the intervention and directing adaptation.
- Training, supervising, and debriefing staff weekly.
- Managing the budget.
- Developing, implementing, and monitoring quality assurance, evaluation and recruitment plans.
- Monitoring recruitment and retention efforts and data collection.
- Requesting technical assistance.
- Explaining **TLC** to stakeholders.
- Conducting weekly staff supervision and annual performance reviews.

TLC requires two Facilitators. Where possible one Facilitator should be a male and the other female. Experiences in delivering the intervention have found that women feel more comfortable and safer discussing issues of sex and sexuality with female Facilitators. If any of the women have been victims of domestic violence or any crimes against women, the presence of a female Facilitator will help to create a safe and supportive environment. (Note: This is applicable when there is a mixed gender group and is not necessary if the group is all male). Lastly, at least one Facilitator should match the ethnicity of the majority of the participants.

The two Facilitators should coordinate their responsibilities for each session and practice together in advance of the session. The two Facilitators need to develop a method of signaling each other if one notes a participant in need of special attention. The Facilitators may have to handle participants experiencing suicidal or homicidal thoughts or be available after sessions to talk with participants if something is bothering them. **TLC** may be emotionally moving or life changing for some participants. Both Facilitators need to be aware and sensitive at all times. It may be necessary for Facilitators to refer participants with serious problems to other places that can help.

5.5 Staffing Patterns - *continued*

A Program Assistant can help out with recruiting clients, placing reminder phone calls, ordering food and supplies, and completing all of the preparations for the sessions.

Some community based organizations train and supervise volunteers who assist in completing the administrative tasks associated with implementing **TLC**. These volunteers need to be trained about the goals and objectives of **TLC** and what happens in each session. If they deal with participants, they need special training on maintaining confidentiality.

5.6 Staff Responsibilities, Skills, and Knowledge

The chart on page 29 lists the key personnel necessary to implement **TLC**, including the number and percent time for each position, responsibilities, and required skills and knowledge. This will assist in developing job descriptions and estimating personnel needs and costs.

Key Personnel Necessary to Implement TLC

TLC PERSONNEL			
POSITION	% TIME	RESPONSIBILITIES	SKILLS & KNOWLEDGE
Program Manager	1 @ 50% (depending on the size of program.)	Maintain program integrity; ensure fidelity to the intervention and direct adaptation; train and supervise staff, and debrief them weekly; manage the project budget; develop, implement, and monitor quality assurance, evaluation, and recruitment plans; monitor recruitment and retention efforts and data collection; request technical assistance; explain program to stakeholders; conduct weekly staff supervision and annual performance reviews.	Supervisory skills; knowledge of cognitive-behavioral theories and techniques; strong program management skills; extensive experience in facilitating groups; ability to train and supervise staff and interact with stakeholders; knowledge of successful recruitment techniques, facilitation skills, the local community, community resources, emergency procedures, and mandatory reporting; sensitivity to youth living with HIV; ability to organize program events; basic evaluation skills; MPH or equivalent preferred.
Group Facilitator(s)	2 @ 50-100%	Facilitate small group sessions; learn TLC curriculum; participate in recruitment and retention efforts; implement quality assurance and evaluation plans; complete appropriate paperwork; organize program-related social events.	Knowledge of facilitation techniques based on cognitive-behavioral principles; knowledge of high risk young adult community; comfort with target population; excellent verbal communication and facilitation skills; knowledge of target population and local resources; understanding of and commitment to the project and its goals; BA in social science or related field preferred.
Program Assistant (optional)	1 @ 50%	Coordinate group session logistics; assist with recruitment and retention efforts and data entry; process all requests for supplies and materials; organize program-related social events.	Solid organizational and budgetary skills; familiar with standard agency procedures for ordering materials; familiar with local area, including office supply and food vendors; AA in social science or related field preferred.

5.7 Characteristics and Skills of Facilitators

The Facilitators will direct the intervention sessions, guiding the participants through the content of **TLC**. It is important to remember that the Facilitators for **TLC** do not operate in the role of counselors. The trained Facilitators need to be clear that **TLC** is a behavioral intervention; the sessions are not counseling sessions, classes, or public health forums. The box below shows a list of skills and characteristics to look for when selecting Facilitators for **TLC**.

Characteristics and Skills of Facilitators:		
Trustworthy	Flexible	Understanding and non-judgmental
Active listener	Empathic and supportive	Interested in working with groups
Good knowledge of group process	Not chemically- dependent: sober or in recovery	Creates warm and welcoming environment
Ability to promote communication	Ability to manage and control problems	Respectful of others and their opinions
Maintains eye contact	Follows up on identified needs	Ability to adapt to changing dynamics in the group
Understanding of group dynamics	Uses humor effectively and appropriately	Ability to adjust agenda times to meet needs of the group
Ability to build rapport	Ability to make appropriate referrals to services	Willingness to learn from the group
Dynamic and friendly	Culturally competent	Respect for confidentiality
Good observer	Patient	Ability to work with people where they are; client centered
Authentic	Knowledge of HIV/AIDS	Aware of own comfort level, skills, and limits
Focus on group needs instead of own personal agenda	Shares and discloses personal information appropriately	Knowledge of challenges dealing with vulnerable young people
Experience working with young people	Experience working with young people of various or undecided sexual orientation	

5.8 Role of Facilitators

The selection of skilled Facilitators is an important part of **TLC**. A Facilitator should have experience working with groups involving people living with HIV. A **TLC** Facilitator could be someone with a bachelor's level training in counseling/mental health work, a psychologist, a social worker, a Licensed Practicing Counselor or a Licensed Chemical Dependency Counselor. Hopefully, the wide range of suggested credentials will facilitate finding a Facilitator and not create implementation barriers.

Roles and responsibilities for a skilled Facilitator include:

1. Manage the operation of the session:
 - Provide knowledge and skills needed.
 - Apply these skills to the session contents and be familiar with the material beforehand.
 - Be on time and stay on time.
 - Manage communications in the session.
 - Be prepared and organized.
 - Have all materials ready for each session and organized so that they can be accessed when needed.
 - Provide a safe emotional space.
 - Be enthusiastic and optimistic, and communicate belief in the intervention.
 - Be a good role model.
 - Be empathic, but stay in role.
2. Recognize and reward positive behavior:
 - Use positive statements to support desired behavior.
 - Use Thanks Tokens to acknowledge participants' positive actions.
 - Support participants' efforts to move their behavior in the desired direction.
3. Challenge disruptive or problematic behavior:
 - Enforce Ground Rules to maintain order and a safe environment.
 - Use group processes to set and reinforce group norms.
4. Elicit participants' assessment of their feelings:
 - Use the Feeling Thermometer to help participants recognize their level of discomfort.
 - Help participants identify the body sensations that accompany their feelings.

5.8 Role of Facilitators - *continued*

5. Encourage participation:
 - Judiciously point out Ground Rules (especially “confidentiality”) to ensure the existence of a safe environment, and help participants feel more comfortable addressing sensitive topics.
6. Show participants how to act effectively:
 - Model the skills **TLC** teaches.
 - Demonstrate coping skills.
 - Use role playing based on the participants’ experiences to help peers learn from each other.
 - Practice problem-solving frequently.
 - Demonstrate effective communication and interactive behaviors, including assertiveness.
 - Help participants practice new ways of thinking, feeling, and acting.
7. Create concern in participants about:
 - Unsafe sexual and substance use behaviors.
 - Other forms of unhealthy behavior, including lack of adherence to health-promoting behavior.
 - Involvement in risky situations and with risky partners.
8. Build group cohesion through:
 - Showing appreciation to participants for their contributions (e.g., Thanks Tokens).
 - Communicating clear expectations regarding how group members treat each other and how they participate—talking, sharing, role playing, checking feelings.
 - Encouraging self-disclosure through supportive statements, teaching communication skills, modeling, using the Feeling Thermometer, and demonstrating acceptance of group members regardless of the feelings and content expressed.
 - Having group members give each other praise, recognize what is positive about each other, provide constructive feedback, and share.

5.9 Staff Training: Facilitation Coordination and Practice

All staff will need to be trained on what **TLC** is and the strategies used in **TLC**. One important component of Facilitator training is coordination and practice. Facilitation coordination and practice is a specially scheduled time when Facilitators hold practice **TLC** sessions. One of the goals of coordination and practice is to give the Facilitators an opportunity to spend time learning the **TLC Implementation Manual** and the intervention materials and handouts before the intervention begins. Facilitators will also want to practice transitions from topic to topic, discussions, and the role plays. In addition, practice and coordination will give the Facilitators a feel for the basic logistics of **TLC** and the time management needs of each session.

During facilitation coordination and practice, Facilitators can also practice managing conflict and other difficult group dynamics. Practice sessions will increase each Facilitator's comfort level with the group process and promote flexibility in the agenda based on the needs of the participants. In addition, practice will help Facilitators assess their facilitation skills. Facilitators should strive to know the **TLC** sessions well enough so that they can use an outline or note cards instead of reading from the **TLC Implementation Manual**. The Program Manager and other relevant staff members may want to observe the practice sessions and provide Facilitators with feedback. Some potential evaluation questions are:

- What went well? Why did it go well?
- What did not go well? Why did it not go well?

Additionally, the practice will provide the Facilitators with the opportunity to assess and evaluate their knowledge of the intervention content. Some sample evaluation questions are:

- Are the purposes of the session's aims and activities clearly understood?
- What will the participants learn at the end of the session?

The end result of facilitation coordination and practice is that the Facilitators will have had the opportunity to improve their facilitation skills and the quality of session delivery.

5.10 Necessary Policies and Standards

Agencies implementing **TLC** should develop a plan for addressing participants who may experience suicidal or homicidal ideation, violent outbursts, or other adverse events. This plan will assist the Facilitators in knowing where and how to refer participants for additional assessment or treatment services. The following points can be included in the agency's plan. This list is not exhaustive, but it does cover the main areas to be addressed.

- Written protocols for handling emergency and non-emergency situations that occur during or after **TLC** sessions, handling suicidal or homicidal ideation and other "duty-to-warn" issues, and identifying appropriate staff or a referral process for immediate assessment.
- Training on these protocols for all staff involved in the **TLC** intervention. This training should be documented for each staff person.
- Provide skills-building training to help intervention staff differentiate between emergency situations and non-emergency situations that may occur during or after a **TLC** session.

5.10 Necessary Policies and Standards - *continued*

- Each agency’s protocol should include mechanisms for referrals and ways to track and follow-up on the referral made.
- Engage the services of a licensed/certified clinician. The agency should have this person provide supervision to the Facilitators and provide ongoing clinical insight.
- In instances where the agency does not have a licensed/certified clinician in-house, referrals should be provided for participants and Facilitators to network with agencies with such services.

Before an agency attempts to implement **TLC**, the following policies and procedures should be in place to protect participants and the agency:

Legal/Ethical Policies

Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners. Agencies are obligated to inform participants of the potential “duty-to-warn” laws. Knowledge of local and state laws regulating needle and syringe exchange programs is also essential. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Cultural Competence

Agencies must make every effort to uphold and respect cultural norms, values, and traditions that are endorsed by community leaders and accepted by the target population.

Confidentiality

A system to protect the confidentiality of those who choose to participate in the program needs to be in place.

Referrals

Agencies need to have adverse events procedures that include appropriate referrals for session participants.

Resource Packet

Participants in **TLC** may have questions and needs that cannot be addressed during the actual sessions. Because of this, agencies may decide to create a Resource Packet to distribute to each participant. The packets should describe services and other resources in their community. If used, Facilitators should encourage participants to make use of these resources and remind them of the packet at the end of each session.

Here is a list of some of the types of materials that might be included.

- Business card or other contact information for the Facilitator and the sponsoring agency.
- Information on the limits of confidentiality and relevant notification laws.

- An introduction to **TLC** and why it is being implemented by your agency.
- A list of key agencies providing services to young people living with HIV/AIDS.
- A variety of resource brochures specific to the community (e.g., information about where in the immediate area to find HIV/AIDS services, assistance with housing, food, medical treatments, prescriptions, etc.).
- Up-to-date information on transmission of HIV, HIV medications, and HIV therapy/treatment.
- Printouts from websites of interest to participants.
- List of contributors of any donated refreshments, gift certificates, or coupons.
- Any other materials that might serve as a resource to participants.

Some agencies have reported that its **TLC** participants do not like to receive take-home materials that mention HIV or AIDS. Implementing agencies should assess the merits and feasibility of posting the Resources Packet on a website with URL not associated with HIV/AIDS.

Data Security

All process and outcome data collected from or associated with participants (including worksheets, progress reports, attendance records, etc.) must be kept in a locked, secure location with only designated program staff able to access it.

Quality Assurance

A quality assurance plan outlining quality assurance and improvement activities should be in place before beginning implementation of **TLC**.

Evaluation

Agencies are strongly encouraged to have an evaluation plan in place before beginning implementation of **TLC**. Both quality assurance and evaluation are discussed in Section 9.

5.11 Sample Implementation Plan for TLC

Task	Capacity and Knowledge Needed	Notes
Conduct needs assessment.	Knowledge of target population's needs; knowledge of similar programs and their outcomes.	
Promote TLC to stakeholders; secure buy-in.	Knowledge of agency mission and prevention vision.	
Identify a TLC champion.	Knowledge of agency decision-making dynamics.	
Network with other agencies and community organizations.	Knowledge of intervention; marketing skills; ability to answer questions; knowledge of community and agencies that impact your community.	
Recruit and hire Facilitators.	Knowledge of intervention and advanced group facilitation skills; knowledge of special needs of young people living with HIV/AIDS.	
Identify possible venues for sessions.	Knowledge of sites frequented by target population; ability to access sites; ability to establish trust with site personnel.	
Develop marketing plan: identify recruitment sites.	Knowledge of target population, places to recruit participants, target population(s) members' preferences; ability to conceive a marketing plan.	
Train Facilitators. Training issues include background to intervention, group facilitation skills, and adapting and facilitating the 16 sessions.	Knowledge of tasks and skills required to implement TLC .	
Begin to secure intervention resources (space, food plan, transportation, child care, incentives, etc.).	Knowledge of the intervention and required materials; knowledge of local and agency resources.	
Schedule facilitation coordination and practice.	Knowledge of the intervention materials and the TLC Implementation Manual .	
Recruit and screen potential participants.	Knowledge of intervention, target population, and places/methods to recruit participants; skills to explain the program; ability to interact with strangers; ability to create trust and elicit information.	
Assemble a community advisory group to assist with tailoring the intervention.	Knowledge of community agencies that service target population; identification of individuals possessing key knowledge and/or community leaders.	

Task	Capacity and Knowledge Needed	Notes
Tailor intervention materials.	Knowledge of intervention; knowledge of demographics of target population; ability to tailor intervention activities for target population.	
Develop an evaluation plan based on agency priorities and funder requirements.	Knowledge of the evaluation expectations of a funding agencies and those desired by the implementing agency; knowledge of the purposes of the evaluation process.	
Develop a quality assurance plan.	Knowledge of quality assurance principles and goals.	
Assemble resource guides and create referral system.	Knowledge of target population needs; knowledge of agency resources; and knowledge of and familiarity with local resources, including personal contacts.	
Obtain incentives and refreshments.	Knowledge of local resources and target population preferences.	
Set up, conduct, and debrief from each session.	Knowledge of session content and materials needed, training on intervention facilitation, high level of facilitation skills, ability to lead a debriefing discussion.	

5.12 Sample Timeline for Implementing TLC

This timeline with specific tasks for implementing one **TLC** module may assist with planning. Weeks 1-6 illustrate the pre-implementation (planning) stage of **TLC** and the subsequent weeks reflect the actual implementation stages.

Timeline	Weeks 1&2	Weeks 3&4	Weeks 5&6	Week 7&8	Week 9&10	Week 11&12	Week 13&14	Week 15&16	Week 17
Identify potential Facilitators	X								
Arrange training for Facilitators	X								
Identify members of the intervention team (Program Manager, admin. staff)	X								
Identify potential venues	X								
Tailor marketing information sheet	X								
Secure buy-in	X								
Select Facilitators and solidify TLC Team		X							
Train Facilitators		X							
Schedule facilitation coordination and practice		X							
Select venue		X							
Market intervention to stakeholders		X							
Begin securing intervention resources		X							
Begin recruiting		X							
Tailor intervention materials as needed			X						
Start facilitation coordination and practice			X						
Schedule sessions			X						
Develop evaluation and quality assurance plans			X						
Screen and select participants				X					
Prepare intervention materials				X					
Assemble Resource Packets				X					
Confirm venue				X					
Arrange snacks / food				X					
Continue facilitation coordination and practice				X					
Schedule debriefing				X					
Create referral system				X					
Confirm participants				X					
Inform participants of session venue and time				X					
Obtain incentives				X					
Arrange room					X				

Timeline	Weeks 1&2	Weeks 3&4	Weeks 5&6	Week 7&8	Week 9&10	Week 11&12	Week 13&14	Week 15&16	Week 17
Practice Session One					X				
Conduct Session One					X				
Debrief Session One					X				
Practice Session Two					X				
Conduct Session Two					X				
Debrief Session Two					X				
Practice Session Three					X				
Conduct Session Three						X			
Debrief Session Three						X			
Practice Session Four						X			
Conduct Session Four						X			
Debrief Session Four						X			
Practice Session Five							X		
Conduct Session Five							X		
Debrief Session Five							X		
Practice Session Six							X		
Conduct Session Six							X		
Debrief Session Six							X		
Practice Session Seven								X	
Conduct Session Seven								X	
Debrief Session Seven								X	
Practice Session Eight								X	
Conduct Session Eight								X	
Debrief Session Eight								X	
Wrap-up									X

5.13 Commonly Asked Questions About Planning to Implement TLC

- 5.1.1 What resources (beyond those included in this package) are necessary to conduct the **TLC** intervention?
- 5.1.2 Do materials for the intervention need to be made by a professional service?
- 5.1.3 How do agencies obtain “buy-in” to implement **TLC**?
- 5.1.4 Who are community stakeholders?
- 5.1.5 Can the modules be implemented in any order?
- 5.1.6 What type of site/room is most appropriate for **TLC**?
- 5.1.7 What are the steps for scheduling sessions for **TLC**?
- 5.1.8 What are cost effective strategies for obtaining condoms and lubricant?
- 5.2.1 How should participants be recruited for **TLC**?
- 5.2.2 Should participants be screened prior to starting **TLC**?
- 5.2.3 Is there a **TLC** attendance policy?
- 5.2.4 What is the minimum number of participants for an intervention cycle?
- 5.2.5 Can a group have participants with different risk factors?
- 5.2.6 Can couples participate in the same group?
- 5.2.7 How should an agency deal with interpersonal interactions within the **TLC** groups?
- 5.2.8 How are different literacy levels dealt with in the intervention?
- 5.3.1 How can an agency retain participants in the **TLC** intervention?
- 5.3.2 How can participant fatigue during **TLC** be avoided?
- 5.3.3 What are some ways to keep the sessions fun?
- 5.4.1 Are incentives a requirement for **TLC**?
- 5.5.1 What happens if only one Facilitator is able to be present?
- 5.5.2 If a potential Facilitator does not have group facilitation experience, how can they get training?
- 5.9.1 How can an implementing agency train staff members who weren't able to attend the **TLC** training?
- 5.9.2 How many sessions need to be implemented to maintain the integrity of the intervention?
- 5.9.3 How much preparation time is needed before each session?
- 5.10.1 Are legal and ethical issues tied to implementing **TLC**?

5.1.1

Q. What resources (beyond those included in this package) are necessary to conduct the TLC intervention?

A. In order to implement **TLC**, agencies will need to acquire the following list of supplies and electronic equipment:

- Colored paper for personal worksheets and other handouts.
- Name badges (for first names, or nicknames only).
- Refreshments.
- Male condoms (latex, polyurethane, natural).
- Female condoms.
- Lubricant (“lube”).
- WD-40.
- Push pins and/or masking tape.
- Pens/pencils.
- Latex dams.
- Resource Packets.
- Easel Paper (Chart pads).
- Markers.
- Small prizes or gifts.

5.1.2

Q. Do materials for the intervention need to be made by a professional service?

A. Handouts used in each session and any reminder notices for participants can be printed on your agency’s color or black-and-white printer. Alternatively, an agency may choose to use a small, local duplicating service.

5.1.3

Q. How do agencies obtain “buy-in” to implement TLC?

A. Securing “buy-in” is crucial because it assures the support of agency administration and facilitates the allocation of agency resources for implementing the intervention.

See Section 5.1 where obtaining “buy-in” for **TLC** is described.

5.1.4

Q. Who are community stakeholders?

A. Stakeholders include an agency’s Board of Directors or Executive Board, staff, or funding sources that have an interest in the successful implementation of this intervention.

Appendix B contains a stakeholder’s checklist that can be used to guide your interactions with stakeholders and help you provide them information on the value of **TLC** and its

5.13 Commonly Asked Questions About Planning to Implement TLC - *continued*

benefits to the people your agency serves. The stakeholder's checklist also contains useful ideas about marketing, recruiting, and implementation steps.

5.1.5

Q. Can the modules be implemented in any order?

A. **TLC** should be implemented in the order in which it was developed: the *Staying Healthy* module first, followed by the *Acting Safe* module. The third module, *Being Together*, is optional and can be implemented last. Materials and technical assistance for the *Being Together* module can be obtained by contacting UCLA's Center for Community Health.

5.1.6

Q. What type of site/room is most appropriate for TLC?

A. **TLC** is designed to be delivered in a private and secure location. The following are suggestions for site selection and room logistics:

- Central location along major transit routes so participants with limited or no access to transportation can easily reach the location.
- Consider avoiding venues that advertise services provided to young people living with HIV/AIDS due to the stigma associated with HIV/AIDS (if that's important to your population).
- A site that is handicapped-accessible.
- Flexible seating arrangement to accommodate a group of twelve in a circle.

The agencies that tested the intervention package used a variety of venues to hold their sessions. The agencies reported that the following were good venues:

- Local conference rooms (at low occupancy times).
- An existing agency office space after hours or during lunch times when staff and/or clients are out of the office.

The agencies reported that the following problems made other venues less than ideal:

- Interruptions, lack of privacy.
- Small space or troublesome room configurations.
- Bad geographic locations.
- Noise.

5.1.7

Q. What are the steps for scheduling sessions for TLC?

A. Some suggestions for scheduling sessions are:

- Identify as many potential venues as possible that can handle the group sessions. Choose venues that have large private meeting rooms that can allow flexible seating accommoda-

tions and additional tables for food, are easily accessible via various transportation methods, and are handicapped-accessible.

- Recruit participants through a variety of methods. Keep in mind the days and times participants are available as well as any additional needs the participants may have. Take into account the availability of the identified **TLC** Facilitators.
- Confirm a venue that can accommodate all your needs and requirements.
- Schedule **TLC** sessions on a day and time that is convenient for participants and Facilitators.

5.1.8

Q. What are cost-saving strategies for obtaining condoms and lubricant?

- A. Condoms and lubricant may be available free of charge from your local health department. Quite often, other agencies are willing to share information on sources of prevention materials, or even combine their orders with yours to obtain volume discounts. Packaging condoms and lubricant in zipper-top bags will add a modest cost. Small one-time packages of lubricants are slightly more expensive than condoms, but should be distributed if your target population has told you that it is important.

5.2.1

Q. How should participants be recruited for TLC?

- A. Each agency should create their own plan that details how participants will be recruited, recruitment venues and locations, recruitment/marketing tools, and the number of participants to be recruited. Some agencies have used: flyers promoting **TLC** at local health clinics; street outreach by staff members; announcements during social gatherings; and outreach to existing clients to tell them about **TLC**. The urban case study agencies also used Internet bulletin boards to recruit participants.

5.2.2

Q. Should participants be screened prior to starting TLC?

- A. Screening participants before beginning a **TLC** group is recommended. Some youth may be experiencing problems that are beyond the scope of the **TLC** group and may require some type of treatment before being ready to participate in a group intervention. Some characteristics that may need to be screened for include: suicidal ideation, homicidal thoughts, severe depression, violent outbursts, etc.

5.2.3

Q. Is there a TLC attendance policy?

- A. Implementing agencies should have an attendance policy that clearly states the agency's expectation that participants attend every session. The attendance policy can be created prior to beginning the **TLC** intervention or it can be determined by the Facilitators and group once the sessions have begun. Each session builds on previous sessions, so missing two consecutive sessions undermines the ability of participants to fully participate in the intervention. Participants who miss more than two sessions may be invited to participate in the next intervention cycle if the agency has the resources to implement additional groups of **TLC**.

5.13 Commonly Asked Questions about Planning to Implement TLC - *continued*

Agencies that tested the **TLC** Intervention Package closed the group after the first two sessions and invited participants who did not show up, an opportunity to participate in a later cycle of **TLC**. Agencies may also consider running concurrent groups as resources allow.

5.2.4

Q. What is the minimum number of participants for an intervention cycle?

- A. A minimum number of participants for **TLC** group session is four. Groups with fewer than four lack the number of participants necessary to adequately stimulate discussions or offer a variety of viewpoints. The maximum number of participants is 12. Too many participants prevents everyone from actively participating in the sessions.

5.2.5

Q. Can a group have participants with different risk factors?

- A. Yes. Often times the risk factors of the participants in the group will be mixed. If the Facilitators are aware of the different types of risk factors present in the group they should tailor the content so that all risk factors are addressed.

5.2.6

Q. Can couples participate in the same group?

- A. No. It is not recommended that couples participate in the same group at the same time. Group members may have issues or problems with their partners that they want to address in the group. They may feel uncomfortable with their partner in the same room and this may also make other group members uncomfortable as well. In addition, the group is not a therapy session for any group member and having couples in the same group could lead to discussions about the couple's personal issues.

5.2.7

Q. How should an agency deal with interpersonal interactions within the TLC groups?

- A. Ground rules establish guidelines for behaviors during the sessions. Participants are strongly advised that they should refrain from developing interpersonal relations of a sexual nature with other **TLC** participants for the duration of the **TLC** intervention.

5.2.8

Q. How are different literacy levels dealt with in the intervention?

- A. **TLC** is a low literacy intervention with minimal reading that can be tailored to meet various literacy levels.

Some suggestions for promoting comprehension:

- Avoid complicated words, syntax, and explanations.
- Use simple terms.

- Designate one Facilitator to spend time with participants who are having a difficult time reading or comprehending forms, cards, or handouts.

5.3.1

Q. How can an agency retain participants in the TLC intervention?

- A. Create a system wherein reminder phone calls, text messages, and/or e-mails are provided periodically between sessions. Other techniques to retain participants include providing food during sessions, allowing for breaks, and providing positive feedback to participants for committing to attend the sessions. Some agencies that implemented **TLC** provided monetary incentives with an extra bonus incentive for those who attend every session. Other strategies include creating a round rule in the first session which states that everyone agrees to come back “one more time”.

Overall, if participants are enjoying the program, they are more likely to return, so keeping a lively interactive group is strongly suggested. Additionally, retention rates tend to be higher when participants feel that their opinions and contributions matter to the group. Providing validation and positive reinforcement to participants will help to increase retention. This can be achieved through using the “Thank Tokens” mentioned earlier. Agencies that tested the package reported giving personal notes to participants at the end of sessions saying “thank you for your participation” in the group. Participants reported really appreciating the personal touch and citing it as a reason for returning to the group.

5.3.2

Q. How can participant fatigue during TLC be avoided?

- A. Taking frequent breaks that allow the participants to stretch, get some water, or grab a snack can help. Another method is to make the sessions very interactive and fun, allowing participants the opportunity to practice their new **TLC** skills and techniques. Facilitators may want to consider using humor appropriately, so participants can laugh and enjoy themselves and the intervention. Facilitators may also acknowledge the length of the session by giving out Thanks Tokens to participants to show appreciation for the time they have committed to the group. Facilitators should keep group members apprised of the time periodically so everyone is on the same page. The best way to avoid fatigue is to keep to the time allocated to each activity in the ***TLC Implementation Manual***.

5.3.3

Q. What are some ways to keep the sessions fun?

- A. Here are some ways to keep the sessions fun:
- Look for ways to incorporate humor at appropriate times during the sessions.
 - Make the condom demonstration fun and exciting.
 - Include humorous tidbits in the welcome back and check-in.
 - Give applause, small incentives, or both, to participants who take part in role plays or get an answer correct.
 - Incorporate energizers, which are located in the appendix of the ***TLC Implementation Manual***.

5.13 Commonly Asked Questions about Planning to Implement TLC - *continued*

Remember that the subject matter discussed in **TLC** can be intense, so including appropriate humor can be a way to de-escalate the tense moments that can occur in the sessions.

5.4.1

Q. Are incentives a requirement for TLC?

A. Incentives are a key characteristic of the **TLC** intervention, but are not required. They can, however, provide extra motivation for young people to keep attending **TLC** group sessions.

The types of incentives will vary by agency based on available funds and the needs of the specific target group. Agencies have used food coupons, cash, and gift certificates. There is no “best” type of incentive—agencies can be creative in choosing incentives while considering their available resources.

5.5.1

Q. What happens if only one Facilitator is able to be present?

A. It is good to have a back-up Facilitator trained and on call should one Facilitator be out ill or experience an emergency situation. The Program Manager may be helpful in assisting during a Facilitator’s absence. It is not recommended that one Facilitator lead a group session.

5.9.1

Q. If a potential Facilitator does not have group facilitation experience, how can they get training?

A. Individuals can take courses offered by the CDC-funded Prevention Training Centers located around the country. Additionally, training on group dynamics and group facilitation can be obtained through courses at a local college or university.

5.9.2

Q. How can an implementing agency train staff members who were not able to attend the TLC training?

A. It is strongly recommended that individuals only receive training through one of two methods:

- Training by UCLA staff familiar with **TLC**.
- Training by individuals who have gone through the Training of Trainers (TOT) for **TLC**.

5.9.3

Q. How much preparation time is needed before each session?

A. We recommend that Facilitators dedicate at least forty-five minutes to one hour to prepare before each group session. This time should be spent considering a number of things. First, review session aims and practice delivering the content areas that are least familiar so that you can estimate the amount of time needed. Practicing a whole session is very useful

and will help Facilitators identify areas that may require additional preparation. If practicing a whole session, allow for two hours.

Second, plan session logistics. For example, know the location of equipment, easel charts, and other intervention materials. Also, photocopy and organize handouts in advance.

Third, decide which Facilitators will cover what material.

The more Facilitators practice mock **TLC** sessions, the more smoothly the sessions will run during implementation. Agencies that have implemented **TLC** reported that several practice sessions allowed Facilitators to establish a flow and rhythm that helped make the sessions run more effectively.

5.10.1

Q. Are there legal and ethical issues tied to implementing TLC?

- A. **TLC** is not an experimental intervention, so there are no human subjects or Institutional Review Board issues associated with its implementation. Every implementing agency has an ethical obligation to promote the welfare of the people it serves and to provide quality care that meets or exceeds local standards. One crucial step in preparing for the intervention is setting up the proper policies and procedures that will protect the implementing agency, the **TLC** intervention team, and the participants. It is important to keep in mind that **TLC** is an intervention that deals with disclosure of HIV status. Agencies implementing **TLC** must know their state laws regarding disclosing HIV status to sexual partners. Agencies must also be familiar with local and state laws regulating the possession and exchange of needles and syringes.



SECTION 6: TLC Budget and Cost Sheet

This section presents information on how to budget direct costs for **TLC**. Direct costs include personnel (staff salary and benefits), rent, utilities, equipment, and program costs (supplies, recruitment, and retention).

Indirect costs are those costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, program or activity, but are nevertheless necessary for the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries are generally treated as indirect costs. Indirect costs vary considerably from one agency to another and different funding streams may or may not reimburse them. Indirect costs are not included in this discussion.

General Costs

As with any intervention, you will have costs for overhead items: space, utilities, insurance, furniture, telephones and phone service, at least one computer, and Internet access. Additional non-personnel intervention-specific expenditures include supplies used for implementing the sessions such as markers, Easel Paper, pencils, and reams of paper (colored and standard white).

A cost sheet has been provided to highlight possible costs associated with **TLC**. This is meant only as a guide. As noted in the previous section, the suggested personnel for **TLC** are a Program Manager, Facilitators, and a Program Assistant. Depending on available agency resources, more staff may be added. The number of times you offer the **TLC** modules and the specific needs of your agency will cause these figures to vary from organization to organization. The provided cost sheet assumes that your agency has access to intervention participants. If this is not the case, you will need to add recruitment costs. It also assumes that there will be no donations, volunteers, or in-kind contributions, and includes cost/values as if everything will need to be paid for by the agency.

6.1 Sample TLC Cost Sheet

Categories for Provider Costs to Implement the TLC Intervention

Categories	Pre-Implementation (start-up)		Implementation (intervention delivery)	
PERSONNEL	# Staff	% time or # hrs/wk (% FTE time spent on intervention)	# Staff	% time or # hrs/wk (% FTE time spent on intervention)
SALARIED				
PROGRAM MANAGER	1	75%	1	50%
FACILITATOR	2	50%	2	100%
PROGRAM ASST.	1	50%	1	50%
FRINGE BENEFITS		25%		25%
FACILITY(IES)		(% time used for intervention)		(% time used for intervention)
RENT				
OFFICE	\$ x	% =	\$ x	% =
SMALL GROUP MEETING SPACE	0		\$ x	# sessions = (inc. pre-sessions)
UTILITIES	\$ x	% =	\$ x	% =
TELEPHONE/FAX	\$ x	% =	\$ x	% =
MAINTENANCE	\$ x	% =	\$ x	% =
INSURANCE	\$ x	% =	\$ x	% =
EQUIPMENT		(% time used for intervention)		(% time used for intervention)
COMPUTER	\$ x	% =	\$ x	% =
COPIER	\$ x	% =	\$ x	% =
EASEL	\$ x	% =	\$ x	% =
EQUIPMENT MAINTENANCE	\$ x	% =	\$ x	% =
INTERNET SERVICE PROVIDER	\$ x	% =	\$ x	% =
SUPPLIES				
POSTAGE & MAILING	\$		\$	
COPYING & PRINTING	\$		\$	
OFFICE SUPPLIES:				
PAPER (WHITE)	1 ream x	\$ /ream =	5 reams x	\$ /ream =
PAPER (COLORED)	0		3 reams x	\$ /ream =
CERTIFICATE PAPER	0		1 pkg. x	\$ /pkg. =
PENS	1 dozen x	\$ /doz. =	3 dozen x	\$ /doz. =
NAME BADGES	0		100 x	\$ /each =
EASEL PAPER	0		2 pads x	\$ /pad =
MARKERS	0		1 pkg. x	\$ /pkg. =
PUSH PINS	0		1 box x	\$ /box =
MASKING TAPE	0		1 roll x	\$ /roll =
POCKET FOLDERS	0		10 x	\$ /each =
CONDOMS				
MALE	0		2 dozen x	\$ /doz. =
FEMALE	0		2 dozen x	\$ /doz. =
LUBRICANT	0			
ANATOMICAL MODELS:				
MALE	10 x	\$ /each =	0	
FEMALE	10 x	\$ /each =	0	
PRINTED MATERIALS				
FORMS	0		3	
INFORMATION SHEETS/FLIERS	5 gross x	\$ /grs. =	0 x	\$ /each =
OTHER MATERIALS				
PRIZES	0		8 x	\$ /each =
CATERING/REFRESHMENTS			80 x	\$ /person =
RECRUITMENT (OF STAFF/VOLUNTEERS)				
ADVERTISING	10 column inches x	\$ /inch =	10 column inches x	\$ /inch =
TRAVEL				
MILES TO/FROM INTERVENTION LOCATION (if other than regular work place)	# miles x	¢/mile =	# miles x	¢/mile =

6.1 Sample TLC Cost Sheet - *continued*

Notes on Categories for Provider Costs

- Intervention delivery costs are based on an average of 10 participants times eight sessions per module. **TLC** should be implemented in the order in which it was developed: the *Staying Healthy* module first, followed by the *Acting Safe* module. The third, optional module, *Being Together*, can be implemented last. Numbers of printed and other materials are calculated as follows: for the complete intervention you will need approximately 10 sheets (forms, handouts, evaluation) per person. For each session you also will need one name badge and one serving of refreshments per participant. One prize is awarded at each session.
- Both Facilitators will need to be compensated for their time recruiting, interviewing participants, training (four days), and practicing during pre-implementation. Intervention delivery time includes review before each session, travel to sessions, session time, and debriefing time, and assumes weekly sessions for eight weeks, plus a week each for preparation and wrap-up.
- Figures are based on one implementation of the complete intervention to one target population.
- As staff turns over, additional money must be allocated for training new staff.



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SECTION 7: Implementing TLC

7.1 Questions and Answers on Implementing TLC

This section contains frequently asked questions addressing issues that may arise during implementation of **TLC**.

- 7.1.1 How can a “debriefing” session improve delivery of **TLC**?
- 7.1.2 How do I deal with disruptive participants?
- 7.1.3 What happens to the group dynamic if some participants do not show up?
- 7.1.4 How should a Facilitator respond to a question if they are unsure of the answer?
- 7.1.5 What if the session runs longer or shorter than the suggested two hours?
- 7.1.6 What kind of refreshments would be appropriate to offer during the session?
- 7.1.7 What are Resource Packets and how are they used?
- 7.1.8 If a Facilitator or group participant is ill should the individual still attend the session?
- 7.1.9 What is the purpose of the Ideal Self concept?
- 7.1.10 The Ideal Self concept was difficult for participants to grasp. Should I continue to use it?
- 7.1.11 What is the F-T-D Framework?
- 7.1.12 How do I use the Feeling Thermometer?
- 7.1.13 How do I use the Thanks Tokens?
- 7.1.14 What are the main objectives of problem-solving and goal setting?
- 7.1.15 How are role plays conducted?
- 7.1.16 What is reframing?
- 7.1.17 What is positive self-talk?
- 7.1.18 Do Facilitators have to follow the script in the intervention manual word for word?
- 7.1.19 Some of the sessions contain many activities. What if I am unable to get to all of them?
- 7.1.20 What is the purpose of the lottery?
- 7.1.21 What if some of the participants do not relate to the relaxation activities?

7.1.22 Can sessions be added to or omitted from **TLC** to cover additional topics?

7.1.23 Why are visual aids used in **TLC**?

The following questions are specific to the *Acting Safe* module.

7.1.24 When do I use anatomical models to properly demonstrate the use of condoms?

7.1.25 There is a lot of talk about drug and alcohol use. What if there are some participants who do not use drugs or alcohol?

7.1.1

Q. How can a “debriefing” session improve delivery of TLC?

A. A debriefing session can be a formal or informal time to process how the group session went, what worked and what did not work, and if any adaptation or tailoring needs to be done before the next session. It is also a time when Facilitators can discuss their own feelings about the session. The debriefing sessions can be done with a Program Manager or other supervisor or can be an informal discussion between Facilitators. The debriefing session can also be used to discuss costs and additional resources needed, if any.

7.1.2

Q. How do I deal with disruptive participants?

- A. There are several methods that can be utilized for dealing with disruptive participants:
- Call for a short break and address the issue with the disruptive participant.
 - One of the Facilitators could excuse himself or herself along with the participant and discuss the issue in another private setting.
 - Redirect/refocus the entire group without singling out any one individual.
 - Refer back to the Ground Rules which should contain agreed-upon appropriate behaviors of all participants.
 - Seat the disruptive participant next to a Facilitator.
 - If action continues or repeats, the participant can be asked to leave the session as a result of their disruptive actions.
 - Refer to the “facilitation skills” section in the *TLC Implementation Manual*.

See the “Suggestions for Handling Problem Behavior” in Appendix D.

7.1.3

Q. What happens to the group dynamic if some participants do not show up?

A. If a participant misses a session it is useful to do a group check-in when they return. By doing this at the front end of the session, other participants will feel more at ease with absent group member’s return and it will eliminate any mystery or question as to why he or she missed the group. However, the group member does not have to share the reason why they missed a session if they do not choose to do so. Agencies testing the intervention package have found that after the initial acknowledgement of a group member’s absence, the group cohesion is generally quickly reestablished and there is no disruption to the group dynamic.

7.1 Questions and Answers on Implementing TLC - *continued*

7.1.4

Q. How should a Facilitator respond to a question if they are unsure of the answer?

- A. When a Facilitator is unsure of an answer to a question, they should inform the participant that they “do not know” the answer to the question, and reassure the participant that they will research the question and get back to him or her at a later time, preferably by the next session. It is very important for the Facilitator to follow-up with the question and answer in the next session to keep a sense of trust and cohesion in the group. If the participant feels valued and acknowledged, they are more likely to return to subsequent sessions.

7.1.5

Q. What if the session runs longer or shorter than the suggested two hours?

- A. The suggested two hours for a session will vary depending on the size of the group and the nature of group cohesion and personalities. Facilitators should implement time management techniques learned during the Facilitator training to keep the group on pace and on topic. Occasionally, a group may finish early. Facilitators may ask participants if they have any additional questions about the session topic and/or the group may end early. If a group is running over, Facilitators may want to inform participants that time is almost up and the discussion can be continued during the next session.

7.1.6

Q. What kind of refreshments would be appropriate to offer during the session?

- A. It is important for implementing agencies to be very cautious and deliberate when planning for the needs of the participants. We recommend that agencies provide some type of refreshments for their participants. Some of the participants may be on treatment regimens that require food frequently. Also, implementing agencies should consider the diets of their participants with multiple health issues. For example, participants who are diabetic may not be able to eat sugary snacks or fruit juices with high fructose content.

The time of the day the intervention is conducted will determine the type of snacks provided. If implementing agencies decide to provide a meal for their participants, it is recommended that the meal be served after the session. If a meal is served before the session, the participants may be sluggish during the session. Furthermore, eating meals during the sessions interferes with full participation in the session.

Implementing agencies that cannot afford to offer refreshments may want to seek donations within their community. Local AIDS service organizations, food pantries/banks and community merchants are great places from which to solicit donations.

7.1.7

Q. What are Resource Packets and how are they used?

- A. A Resource Packet can be distributed to **TLC** participants to help answer questions and needs that may not be covered during the **TLC** sessions.

See section 5.10 for more information and suggestions of what to include in a Resource Packet.

7.1.8

Q. If a Facilitator or a participant is ill should the individual still attend the session?

- A. **TLC** is a small-group intervention for young people living with HIV/AIDS. This means the participants have compromised immune systems. If any participant is ill, he or she should be excused from the session to protect their health and the health of the other participants. If several participants are ill you may need to cancel the group until all participants are able to attend and participate. If one Facilitator is ill the sessions can continue with the back-up Facilitator. If a back-up is not available, the other Facilitator should consider running the group alone.

7.1.9

Q. What is the purpose of the Ideal Self concept?

- A. Identification of his or her Ideal Self helps participants pinpoint their values as they relate to the way they would like to see themselves behave. Participants are asked to consider those values as they think about the ways they would like to act in specific situations. The Ideal Self is used as a decision-making guide to help motivate and personalize behavior change. Appeals to one's Ideal Self occur throughout the sessions.

7.1.10

Q. The Ideal Self concept was difficult for participants to grasp. Should I continue to use it?

- A. The Ideal Self is a core element of the **TLC** intervention and must be used throughout the sessions as written. If participants have trouble grasping the concept or do not seem to be following the exercise, Facilitators should ask the group if anyone can explain the purpose of the Ideal Self and generate a discussion to identify where the discomfort lies. Facilitators may also choose to model their own version of the Ideal Self and illustrate how the exercise is useful and pertinent to the intervention.

7.1.11

Q. What is the Feel-Think-Do Framework? (F-T-D)

- A. The Feel-Think-Do Framework (F-T-D) is used to support emotional awareness and regulation. **TLC** links feelings, thoughts, and actions as key concepts in making positive and adaptive changes in various aspects of daily life. **TLC** is based on the idea that when something happens, we have a feeling (body reaction) about it, a thought about it, and we do something about it. It is used in every **TLC** session. See the full description of F-T-D in Section 3.

7.1.12

Q. How do I use the Feeling Thermometer?

- A. While becoming more aware of their feelings, youth often need help to recognize, name, discuss, and appropriately express those feelings. Without these skills, the youths' intense feelings can interfere with their ability to make good decisions and act safely.

The Feeling Thermometer helps participants assess and discuss their feelings more effectively during a session. The Feeling Thermometer is a graphic design resembling a fever

7.1 Questions and Answers on Implementing TLC - *continued*

thermometer that has been enlarged and reproduced on a poster and displayed on the wall during every **TLC** session. The highest measurement on the Feeling Thermometer is 100, and it represents the most discomfort one can imagine feeling. That discomfort may be extreme anger, anxiety, excitement, nervousness, depression, or any other emotion that is experienced as discomfort. The bottom measurement is zero, and this represents a total lack of discomfort, whether the associated feeling is happiness or calm or something else.

Facilitators should use the Feeling Thermometer to allow participants to better identify and discuss their feelings and better associate those feelings with a bodily response. The person at or near zero is better able to think and make decisions regardless of the particular emotion. After reviewing the Feeling Thermometer with the participants, Facilitators should ask them to identify ways to reduce the level of the reading on the Feeling Thermometer. If they are extremely uncomfortable, they can practice a relaxation technique as outlined in the session. The relaxation technique will reduce the level of discomfort experienced.

Facilitators may choose to take a Feeling Thermometer “read” of participants’ feelings more frequently than suggested in the intervention manual, and should make sure to do at least one Feeling Thermometer check during each activity.

A complete guide to the using of the Feeling Thermometer is included in the ***TLC Implementation Manual***.

7.1.13

Q. How do I use the Thanks Tokens?

- A. Facilitators should use Thanks Tokens frequently in each session to provide positive affirmation to the participants. Behaviors that are noticed and encouraged by others increase in frequency. Those that are not noticed or are punished usually decrease. This process generally occurs without awareness, and encouragement can be as simple as a smile. The tokens are a visible reminder of our thanks and our appreciation.

Facilitators give each participant an equal stack of the tokens at the beginning of each session. Participants sit in a closed circle as a discussion or activity is underway. When anyone says or does anything someone else likes or agrees with, finds encouraging, causes him or her to think, etc., he or she hands the person a token. It is best when the person explains why the token is being given. The tokens are not “turned in” at the end of the session for something of value. Simply receiving a large number of tokens from their peers and making others feel good about themselves leaves most participants with positive feelings about themselves at the end of the session.

The key to everyone using the Thanks Tokens rests with the Facilitators’ comfort with them. If the Facilitators take tokens seriously and use them at every opportunity to offer positive encouragement, the youth will also respect their value and will actively use them. Note that we recommend using Thanks Tokens in every session, to encourage all participants to give positive feedback to each other.

Both the Feeling Thermometer and Thanks Tokens are also used in **Street Smart**, another evidence-based intervention available from CDC’s Prevention Research Branch-Replicating

Effective Programs. The same techniques are used in both interventions however, their explanations in this manual are more detailed and reflect insight gained from field-testing the **TLC** intervention.

7.1.14

Q. What are the main objectives of problem-solving and goal setting?

- A. Problem-solving and goal setting occur in every session and are important techniques that improve participants' lives. Participants are invited to bring up general problems they may be seeking solutions to or a difficult problem related to one of the sessions. The group chooses one of the problems brought up and applies the SMART Problem-Solving Steps by selecting a goal, identifying barriers and planning the next steps. The process can be applied to a broad range of personal problems and provide participants with a life skill that they can use in everyday life.

Short- and long-term goal setting, related to each session's topic, allows participants to choose something they'd like to accomplish between sessions that suits their own circumstances. There are goal setting guidelines described in the **TLC Implementation Manual**. These guidelines include setting goals that are specific, measurable, appropriate, realistic, and have an end point or time when the goal can be completed.

7.1.15

Q. How are role plays conducted?

- A. Part of **TLC's** core elements, role plays provide an opportunity for participants to teach and practice coping skills that are essential to the intervention. The Facilitators set-up the role play and explain that they provide an opportunity for the participants to act out how they would handle the situation. The Facilitators assign the roles and provide time limits for the role play. The following are the steps to conducting role plays:

- Describe and discuss the scenario.
- Ask for volunteers to act out a role play.
- Ask the participants to demonstrate how they might have handled the situation described and what they would have done or said differently.
- Instruct participants to use their own words and ideas.
- Have participants play the scene.
- Conduct one or two role plays for each scene, using different volunteer participants each time if possible.
- Debrief the role play by asking each participant one thing they liked and what they would do differently.

If none of the participants are willing to volunteer for the role plays, the Facilitators can do the role play themselves. However, this should be done as seldom as possible.

Facilitators should make every effort to avoid stereotyped role playing. Many of the activities involve role plays between persons with specific characteristics. Be sure that these exercises do not stereotype individuals by gender, age, and/or race. Reverse stereotype roles whenever possible. For example: "Let's have the woman this time be the one who doesn't want to use a condom." Also have females role play male roles and vice versa. Fast-paced

7.1 Questions and Answers on Implementing TLC - *continued*

changing during these role-reversals can help to reduce the possibility that the youth slip into stereotypical roles.

If a session's suggested role play does not seem to apply to your group, ask participants to create a role play scenario from their own experiences that may be more applicable and follow the same steps as outlined above.

7.1.16

Q. What is reframing?

A. Reframing is a coping skill taught in **TLC**. Most problems can be improved by the way in which the problem is understood. Problems can be framed as disasters, or in terms of the opportunities a problem presents. **TLC** participants are taught how to frame problems in a positive manner.

Viewing the arousal one feels when going on a job interview as excitement at the possibility of becoming one's Ideal Self through new employment instead of nerves, is one example of reframing.

Another form of reframing is recasting. For example, saying no to a partner's advances for unprotected sex can be recast as protecting a partner and future children from HIV.

7.1.17

Q. What is positive self-talk?

A. Positive self-talk is a coping skill taught in **TLC**. Sometimes a situation cannot be changed, however, what we say to ourselves about the situation can help us cope with it more effectively. Just as behaviors may be practiced in role play situations, young people can learn to talk to themselves in a positive manner, relaxing themselves, and helping themselves to manage a risky situation more effectively.

In particular, catastrophic thinking, a spiraling of negative expectations for oneself and anticipation that the worst possible outcome will occur, can be avoided by using positive self-talk.

7.1.18

Q. Do Facilitators have to follow the script in the intervention manual word for word?

A. Facilitators are encouraged to become very familiar with the content of the intervention and not read the script word for word. Facilitators can present the material in their own words, using language familiar to the target population while making sure to touch upon the main points. Exact scripted language is not necessary as long as **TLC's** core elements are maintained. We recommend putting session notes on index cards. However, Facilitators should not use index cards until they have become familiar with the intervention content. Using the script as written is encouraged until Facilitators feel confident with the intervention.

7.1.19

Q. Some of the sessions contain many activities. What if I am unable to get to all of them?

- A. Facilitators should practice the sessions as much as possible to become familiar with the material. During the practice sessions, Facilitators should time themselves during each activity to ensure they are sticking with the appropriate time allotments. If time is running out for an activity, Facilitators can remind participants that there is still more material to cover and that the discussion can be picked up again later or during the next session. Facilitators should be sure to keep a record of issues that may need to be revisited.

7.1.20

Q. What is the purpose of a lottery?

- A. The lottery is a tool to help participants stay excited about coming to **TLC**, a way to build and maintain group cohesion and a way to reward participants who are on time to a group. Lottery drawings can be held during a break, at the end or at the beginning of a session. Lottery prizes provide positive reinforcement for youth and can be items that young people may enjoy. Prizes can range from key chains, or stickers, to gift cards and games.

7.1.21

Q. What if some of the participants do not relate to the relaxation activities?

- A. Facilitators should practice using these techniques with each other, agency staff, and family and friends as possible. The more comfortable the Facilitator is with the relaxation techniques, the better the response will be from group members. Relaxation techniques are an important tool in the **TLC** intervention. If group members do not respond well to the techniques provided, ask participants what relaxation techniques they have used in the past. Facilitators may choose to start with a review of relaxation techniques that participants are familiar with and see if they can be integrated with the **TLC** relaxation techniques.

7.1.22

*Q. Can sessions be added to or omitted from **TLC** to cover additional topics?*

- A. No. Sessions may not be added or omitted. **TLC** is an evidenced-based intervention and sessions cannot be added to cover additional topics. All eight sessions must be delivered as written. Adding or omitting sessions or topics will compromise the integrity of the intervention.

7.1.23

*Q. Why are visual aids used in **TLC**?*

- A. Visual aids like the wall charts supplied in the **TLC** Intervention Package can assist with explaining a concept while also making it simple and easy to remember. There are several such aids in the intervention package. Feel free to create your own that are appropriate to your target population as long as you do not change the core elements of the intervention.

7.1 Questions and Answers on Implementing TLC - *continued*

The following questions are specific to the *Acting Safe* module.

7.1.24

Q. When do I use anatomical models to properly demonstrate the use of condoms?

A. The proper use of condoms (both male and female) is demonstrated in Session Three of the *Acting Safe* module. It is important that implementing agencies are teaching skills that are in accordance with current CDC guidelines. In Session Three, participants will discuss the pros and cons of condom use as well as demonstrate the proper use of condoms. Facilitators should review the female condom demonstration even if there are no females in the group. Often times, the female condom is used by male partners during anal sex.

7.1.25

*Q. In *Acting Safe*, there is a lot of talk about drug and alcohol use. What if there are some participants who do not use drugs or alcohol?*

A. Sometimes Facilitators may encounter a participant who does not use drugs or alcohol. The Facilitator can encourage the participant to modify the exercises that deal with drugs and alcohol. They can help the participant substitute some other habit they feel they would like to work on, such as food, cigarettes, gaming, Internet chat rooms, etc. Another alternative Facilitators can employ is to have participants work towards maintaining their abstinence from drugs and alcohol.

7.2 Special Issues in Working with HIV-Infected Individuals

When working with immune-compromised individuals, there are several issues that need to be considered. During the course of **TLC**, participants may be absent as a result of health events such as doctor's visits, HIV/AIDS related illness, or another issue related to their disease. Agencies and Facilitators should also be aware of the side effects caused by HIV medicines. These side effects can impact the physical, emotional, and mental well-being of group participants. An agency may wish to establish attendance policies to deal with the absences or the cancellation of group sessions.

7.3 Handling Problem Behaviors

Youth may exhibit problem or disruptive behavior during a group. In most cases, assertive facilitation skills will be sufficient to refocus behavior to the task at hand. Section 5.10 discusses the emergency plans an agency should have in place before an agency attempts to implement **TLC**.

Appendix D contains "Suggestions for Handling Problem Behaviors." This table illustrates possible problem behaviors that could occur in a group and ways of dealing with them.



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SECTION 8: Tailoring TLC

8.1 Ways to Tailor TLC

Once **TLC** is adopted by an agency, its actual impact will depend on how it is implemented to meet the needs of the agency and the community. It is important to achieve a balance between adapting the intervention to suit local needs and maintaining the core elements and key characteristics that made the original intervention successful.

The process of adapting **TLC** to meet the needs of local communities is called tailoring. Tailoring involves customizing the delivery of the intervention to agency circumstances and ensuring that messages are appropriate for target populations without altering, deleting, or adding to the intervention's core elements. Tailoring ensures the cultural appropriateness of the intervention and guarantees that messages are suitable for target populations.

8.2 Using a Community Advisory Group to Tailor TLC

One way of effectively tailoring **TLC** is by convening a community advisory group of young adults living with HIV/AIDS. The advisory group could help:

- Suggest different delivery methods to strengthen the intervention for their community.
- Identify possible peer Facilitators.
- Provide appropriate language and terms.
- Suggest questions for the initial interview and assessment of participants.

The community advisory group could also suggest ways to tailor **TLC**'s key characteristics without compromising the integrity of the intervention's core elements. The key characteristics of **TLC** can be found in Section 4.2.

8.3 Commonly Asked Questions

- 8.1.1 What is tailoring?
- 8.1.2 What is a marker of successful tailoring?
- 8.2.1 What is an effective means of tailoring **TLC**?

8.1.1

Q. What is tailoring?

- A. Tailoring is the process of customizing delivery of interventions to agency circumstances and ensuring that messages are appropriate for target populations without altering, deleting or adding to the intervention's core elements. Tailoring ensures the cultural appropriateness of the intervention and guarantees that messages are suitable for target populations.

8.1.2

Q. What is a marker of successful tailoring?

- A. Successful tailoring achieves a balance between adapting **TLC** to suit local needs and maintaining the core elements and key characteristics that made the original intervention successful.

8.2.1

*Q. What is an effective means of tailoring **TLC**?*

- A. Effective tailoring of **TLC** can be accomplished by convening a community advisory group of young adults living with HIV/AIDS to assist with adapting the intervention.



SECTION 9: Evaluating TLC

There are several different types of evaluation that an implementing agency may want to conduct. The types of evaluation an agency chooses will depend on agency priorities and funder requirements. Evaluation options may include: 1) needs assessment; 2) process monitoring; 3) process evaluation; and 4) outcome monitoring.

There are two key reasons to evaluate a program or intervention: accountability and improvement. Accountability could be to the community, staff, clients, or a funding source. Implementing agencies must also consider their ethical obligation to properly implement any program or intervention. Evaluation also helps improve the quality of intervention delivery. Evaluation shows the agency what worked and what did not work, information valuable in helping agencies fine tune their programs. Agencies should consult funder requirements for evaluation as needed.

9.1 Needs Assessment

Conducting a needs assessment is the process of collecting data that describes the target population and the factors that put them at risk. This type of evaluation is conducted before implementing **TLC** and is used to provide data on the need for **TLC** in a particular community or at a particular agency.

9.2 Process Monitoring

Process monitoring is the process of collecting data that describes the characteristics of the population served, the services provided, and the resources used to deliver those services. Process monitoring answers such questions as:

- How many sessions were delivered?
- What resources were used?
- What additional resources are needed?

Process monitoring serves as a supplement to the routine data collected on the number of people who attended, their gender, race/ethnicity, risk behaviors, age, etc. It can also address issues around recruitment and retention.

9.3 Process Evaluation

Process evaluation aids an agency in determining how closely the core elements were implemented and documents the tailoring that was done for the population and agency. Process evaluation ensures that an agency is delivering **TLC** and not a variation of the intervention. Some sample process evaluation questions include:

- Was each core element maintained?

- Were the sessions delivered as described in the *TLC Implementation Manual*?
- Was the intended target population enrolled?

9.4 Outcome Monitoring

Outcome monitoring, when required and appropriate, is the process of collecting data such as participant knowledge, attitudes, skills, or behaviors before and after the intervention. Outcome monitoring cannot be finished until agencies have completed: a needs assessment formative evaluation; process monitoring and process evaluation; and intervention delivery as planned. Outcome monitoring is intended to answer the question:

- Were there any changes in the participants' behaviors following the intervention?

Using the same evaluation form to monitor participants' behaviors before and after the intervention is one way to assess short-term change. Behavior change is often gradual and incremental, so participants' responses to the intervention may not be immediate or dramatic. We encourage agency staff to discuss their own experiences and to share information on challenges and successes that may occur in relation to the intervention.

9.5 Sample Outcome Monitoring and Evaluation Forms

Appendix E contains sample questionnaires that agencies may choose to use as a model for developing an evaluation tool for **TLC**. Agencies should consult their funders for evaluation requirements and standards.



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Appendix A

Articles on Original Research

Rotheram-Borus, M. J., Lee, M. B., Murphy, D. A., Futterman, D., Duan, N., Birnbaum, J. M., Lightfoot, M., and the Teens Linked to Care Consortium. (2001). Efficacy of a preventive intervention for youths living with HIV. *American Journal of Public Health*, 91:400-405.

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Rotheram-Borus, M. J., Murphy, D. A., Wight, R. G., Lee, M. B., Lightfoot, M., Swendeman, D., Birnbaum, J. M., and Wright, W. (2001). Improving the quality of life among young people living with HIV. *Evaluation & Program Planning*, 24:227-237.



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Efficacy of a Preventive Intervention for Youths Living With HIV

ABSTRACT

Objectives. HIV transmission behaviors and health practices of HIV-infected youths were examined over a period of 15 months after they received a preventive intervention.

Methods. HIV-infected youths aged 13 to 24 years (n=310; 27% African American, 37% Latino) were assigned by small cohort to (1) a 2-module ("Stay Healthy" and "Act Safe") intervention totaling 23 sessions or (2) a control condition. Among those in the intervention condition, 73% attended at least 1 session.

Results. Subsequent to the "Stay Healthy" module, number of positive lifestyle changes and active coping styles increased more often among females who attended the intervention condition than among those in the control condition. Social support coping also increased significantly among males and females attending the intervention condition compared with those attending the control condition. Following the "Act Safe" module, youths who attended the intervention condition reported 82% fewer unprotected sexual acts, 45% fewer sexual partners, 50% fewer HIV-negative sexual partners, and 31% less substance use, on a weighted index, than those in the control condition.

Conclusions. Prevention programs can effectively reduce risk acts among HIV-infected youths. Alternative formats need to be identified for delivering interventions (e.g., telephone groups, individual sessions). (*Am J Public Health*. 2001;91:400-405)

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Youths represent about 50% of all HIV infections worldwide¹ and 18% of reported HIV cases in the United States.² Nationally, there are about 110000 youths living with HIV.³ On the basis of data from seropositive adults,^{4,5} we anticipate that at least one third of these youths may continue their transmission behaviors after learning their serostatus.⁶ HIV-infected youths who do not change their sexual risk acts or injection drug use may both infect others and become reinfected with new viral strains.⁷ Therefore, it is important to change the health behavior and transmission acts of youths with HIV, both for their self-preservation and for the prevention of transmission to others.

With those considerations in mind, we designed and evaluated an intervention for HIV-infected youths consisting of 2 modules delivered in sequence. Based on the results of an extensive qualitative study of such youths,^{8,9} the intervention began with "Stay Healthy," a 12-session module that aims to increase the positive health behaviors of youths with HIV.¹⁰ The intervention was conducted from 1994 to 1996, before the introduction of highly active antiretroviral therapy.¹¹ Even then, the long-term survival of HIV-infected persons was associated with healthy lifestyles¹² and assertively managing health regimens and relationships with health care providers.¹³ Since the introduction of highly active antiretroviral therapy, changes in health behavior are even more important because of the negative consequences of sporadic adherence to these medications,¹⁴ as well as the potential reductions in transmission because of decreased viral loads.

The second module of the intervention, "Act Safe" (11 sessions), aims to enhance altruistic motivations to reduce transmission acts. This module was based on previous successful interventions to reduce sexual and substance-use risk acts with seronegative persons.¹⁵

The Social Action Model,¹⁶ which was used as the theoretical basis of the interven-

tion, was based on an extensive qualitative study of HIV-infected youths⁸ and studies with seropositive adults.^{15,17,18} This model takes into account contextual factors as it focuses on improving affective states that influence self-regulation (e.g., coping) and building skills to improve self-regulation (negotiation skills, self-efficacy).¹⁵

As shown in Figure 1, assessments were conducted before the first module ("Stay Healthy"), between the 2 modules, and after the second module ("Act Safe"). This design allowed us to assess HIV-infected youths' response to the "Stay Healthy" module alone, as well as to assess their response to both modules.

Methods

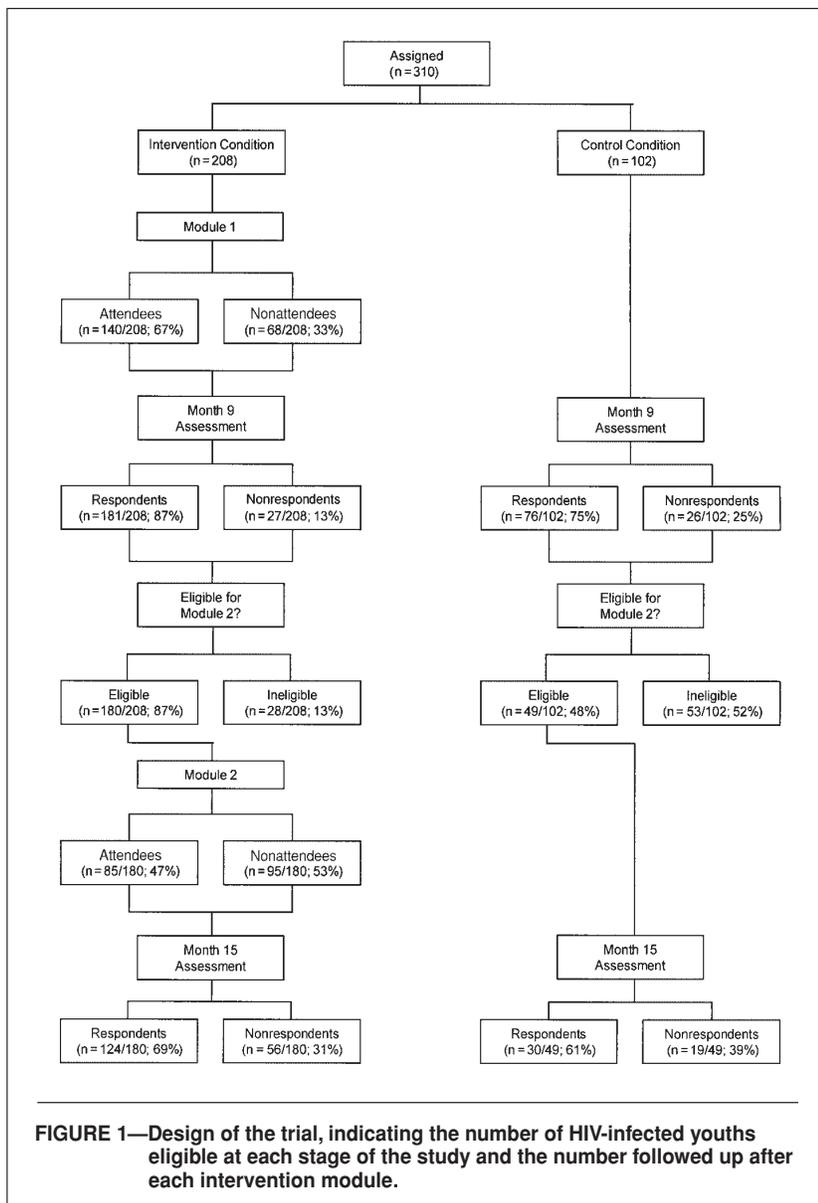
Participants and Assignment

The study was conducted at 9 adolescent clinical care sites in 4 AIDS epicenters: Los Angeles, New York, San Francisco, and Miami. Over a 21-month period (1994 to 1996), 351 of the 393 HIV-infected youths who received care at the sites were recruited after giving informed consent (25 [6.4%] refused participation; 17 [4.3%] were too ill). Parental consent was obtained for nonemancipated youths younger than 18 years.

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Two baseline assessments were conducted at a 3-month interval to establish the stability of risk behaviors, with an incentive of \$20 to \$25 per assessment. Five HIV-infected youths were too sick to participate, and 36 were lost to follow-up before the second baseline. The remaining 310 youths participated in the study: 126 from Los Angeles, 91 from New York, 49 from San Francisco, and 44 from Miami.

Successful HIV interventions with youths have generally been delivered in a small-group format^{15,19}; following this design, we delivered our intervention in small groups (cohorts). Cohorts of about 15 HIV-infected youths each were assigned sequentially to the intervention and control conditions. It took several months to assemble a sufficient number of youths to

form a cohort; in 7 of 9 sites, the last cohort was assigned to the intervention condition. Therefore, across the 9 sites, there were 16 cohorts in the intervention condition (n=208) and 9 cohorts in the control condition (n=102).

Given the sequential nature of the assignment, there is a concern about imbalance between the intervention and control conditions. We conducted regressions to assess the potential bias that might emerge over time during participant recruitment, regressing each risk behavior reported at the baseline interview on the order of entry into the study. No significant time trends were found.

The second baseline interview was conducted before assignment to the intervention condition. As shown in Figure 1, the first mod-

ule of the intervention, “Stay Healthy,” was then delivered to the youths assigned to the intervention condition over a period of 3 months. Youths in both conditions were reassessed at month 9. Among the 310 youths initially assigned, 257 (83%) were reassessed successfully at this time, 181 in the intervention condition and 76 in the control condition (Figure 1).

Module 2 (“Act Safe”) of the intervention was then delivered over a period of 3 months, and youths were reassessed at month 15. Because the duration of the study was limited, 77 youths were recruited too late to participate in module 2, and 4 were ineligible owing to illness or death. The remaining 229 youths (180 in 14 intervention cohorts and 49 in 5 control cohorts) were eligible to participate in module 2. Among these, 154 (67%; 124 in the intervention and 30 in the control condition) completed the month 15 assessment after module 2.

Intervention

Module 1 focused on coping with learning one’s serostatus, implementing new daily routines to stay healthy, issues of disclosure, and participating in health care decisions. Module 2 aimed to reduce substance use and unprotected sexual acts by having youths identify their risk behavior triggers and modify their patterns of substance use as well as increase self-efficacy of condom use and negotiation skills.

A detailed manual (available online at <http://chipts.ucla.edu>) guided the 2 intervention modules, which comprised 23 sessions of 2 hours each.¹⁰ Each participant received \$10 for the first session attended in each module and \$2 increases in incentives for subsequent sessions.

The intervention was usually delivered by 2 facilitators, 1 male and 1 female. The cohorts were mixed according to sex. The facilitators received intensive training of 3 days for each module from teams of experienced cognitive-behavioral intervention researchers. They also received ongoing supervision. The training included review of the study’s theoretical orientation, the intervention manual, and videotapes of model sessions, as well as practice in conducting the intervention.

Quality assurance ratings were conducted from randomly selected videotapes of sessions; ratings for more than 80% of the sessions exceeded criteria for content and process measures of fidelity. On assessments conducted at sessions 5 and 11 of each module, youths in the intervention reported liking their sessions (mean=4.2 on a scale of 1–5); they also rated their facilitators as highly trustworthy (mean=4.2 on a scale of 1–5).

Across both modules, 151 of 208 youths (73%) assigned to the intervention condition

attended at least 1 session (71 attended module 1 only, 22 attended module 2 only, and 58 attended both). Intervention attendees were those assigned to the intervention condition who attended at least 1 session; intervention nonattendees were those assigned to the intervention condition but who never attended a session. Among those who attended at least 1 session in module 1, the mean number of module 1 sessions attended was 7.7 (SD=3.55); 70% attended 6 or more sessions (median=9) out of a total of 12. Among those who attended at least 1 session in module 1 (n=80), the mean number of module 2 sessions attended was 7.6 (SD=3.2); 73% attended 5 or more sessions (median=8) out of a total of 11. Youths in the control condition received standard care at the adolescent clinical care sites and received the intervention at the study's conclusion.

Assessments

Data were collected by an ethnically diverse team of trained interviewers who used computer-assisted interviewing. Quality assurance ratings were conducted from randomly selected audiotapes; 91% met criteria on ratings of completeness, positive tone, and crisis referrals. For all assessment domains, activities reported for the previous 3 months are defined as "recent" behaviors.

We derived 3 indices of health behavior: (a) a weighted index of medical care contacts (the weighted sum of the number of nights [n] for a hospital stay [weight of 5], the number of clinic, office, or emergency room visits [n] [weight of 4], the number of home health care visits [n] [weight of 3], the number of personal support for everyday tasks [n] [weight of 2], and the number of phone consultations [n] [weight of 1] [$\alpha=.62$]); (b) the number of medical appointments missed; and (c) the number of positive lifestyle changes ($\alpha=.71$) (n=12 potential behaviors; e.g., balanced diet, exercise, vitamins, adequate sleep).

We also examined 3 health status measures: (a) T-cell count; (b) physical health symptoms, a summary count of 23 physical symptoms ($\alpha=.88$, $r=0.70$ with chart review of 31 HIV-infected youths)²⁰; and (c) physical health distress score, calculated as a mean of the intensity (range=0–5) of each symptom ($\alpha=.90$).

We assessed coping style with a modified version of the Dealing with Illness Inventory,²¹ with 37 items rated on a 1-to-5 Likert scale and factor analyzed into 7 factors: positive action (10 items; $\alpha=.88$), social support (5 items; $\alpha=.77$), spiritual hope (4 items; $\alpha=.74$), passive problem solving (5 items; $\alpha=.75$), self-destructive escape (5 items; $\alpha=.81$), depression/withdrawal (4 items; $\alpha=.66$), and nondisclosure/problem avoidance (4 items; $\alpha=.66$).

On the basis of extensive sexual history data, we derived the following 4 indices: (a) no recent sexual risk (abstinence [no vaginal or anal intercourse] or 100% condom use over the last 3 months), (b) the number of sexual partners—total count and separate counts by serostatus, (c) the percentage of vaginal and anal sex acts unprotected by condoms with HIV-negative partners, and (d) the percentage of partners to whom disclosure of serostatus was made before intercourse.

On the basis of extensive substance-use data, we derived the following 6 indices: (a) use of alcohol and marijuana only, (b) use of hard drugs, (c) a weighted index of drug use (derived as the sum of the frequency of the use of each drug category, weighted as follows: marijuana=1, amphetamine/stimulants=2, steroids=3, crack/cocaine=4, heroin=5),^{22,23} (d) symptoms of abuse and dependency, (e) entry into and completion of substance-use treatment, and (f) a sum of the number of different drugs used.

Emotional distress was assessed with the Brief Symptom Inventory,²⁴ a 53-item, reliable index of mental health symptoms ($\alpha=.97$).

Data Analysis

We conducted as-treated analyses^{25,26} comparing intervention attendees vs control subjects and intervention attendees vs intervention nonattendees. (Results of intent-to-treat analyses are similar on all outcomes, except for the weighted substance use index for module 2, and are available from the authors.) We used mixed-effects analyses of covariance models to compare continuous postintervention scores across the cohorts, controlling for baseline scores (the second baseline), city, sex, and ethnicity as covariates and treating the cohort as a random effect. We report the adjusted mean outcomes for each condition (intervention attendees, control subjects, intervention nonattendees), adjusted for baseline scores, city, sex, and ethnicity. Similarly, we used mixed-effects logistic regression models to compare categorical postintervention outcomes, controlling for baseline status, city, sex, and ethnicity and treating the cohort as a random effect. We interpreted the intervention effect by using the relative effect size, defined as the intervention effect (the difference between the score of youths in the intervention condition and in the control condition) divided by the score of youths in the control condition, converted into a percentage.

We examined the association between each outcome and the number of intervention sessions attended among intervention attendees to assess the dose–response relationship.

No significant associations were found, most likely because of the relatively high attendance among intervention attendees.

Results

Table 1 describes the HIV-infected youths at the baseline assessment (n=310); the subgroup of youths available for the module 1 analysis is very similar to the group of those assigned at baseline (n=257). At baseline, most participants (72%) were male; 88% of these males were gay or bisexual. The youths ranged in age from 13 to 24 years (mean=20.7; SD=2.1); females were younger than males by about 1.5 years ($P<.001$). Most youths (64%) belonged to ethnic minority groups, 55% had graduated from high school, 31% were currently enrolled in school (mean=11th grade; SD=2.31), and 84% had been employed. On average, youths had tested seropositive for HIV more than 2 years before recruitment (mean=2.1; SD=2.0; median=1.4 years).

We conducted extensive analyses to assess the presence of selection bias, comparing subgroups by assignment, attrition, and participation at each module (results available from the authors). Although the intervention assignment procedure was not randomized, it was successful in producing subgroups that were comparable throughout the study. Only 3 differences were found: (1) the intervention and control conditions were not balanced by site ($\chi^2_6=29.1$; $P<.001$), because 7 of 9 sites ended with an intervention cohort; (2) because Miami had more female HIV-infected youths, and youths from Miami were not eligible for module 2, more males attended only module 1 ($\chi^2_2=11.3$; $P<.05$) compared with other groups; and (3) intervention attendees were more likely to use social support as a coping strategy (an outcome measure) at baseline. City, sex, ethnicity, and baseline status were controlled for in all analyses; therefore, those differences do not confound our findings.

Table 2 summarizes the as-treated analyses comparing intervention attendees, intervention nonattendees, and control subjects.

Module 1: "Stay Healthy"

On average, youths had missed 1 medical appointment (SD=1.2) in the previous 3 months. The most commonly cited reason for missing appointments was ease of rescheduling. When physical health status was controlled for, there were no differences in missed appointments across conditions. T-cell counts, the number of physical health symptoms, and distress associated with physical health symptoms were similar across conditions.

TABLE 1—Baseline Characteristics and Risk Behaviors of Study Participants in a Preventive Intervention for Youth Living With HIV

	Intervention Attendees (n=140)	Controls (n=102)	Intervention Nonattendees (n=68)	Overall (n=310)
Mean age, y (SD)	20.7 (2.1)	20.6 (2.2)	21.0 (1.9)	20.7 (2.1)
12–17, % (n)	7 (10)	10 (10)	4 (3)	7 (23)
18–20, % (n)	34 (47)	31 (32)	31 (21)	32 (100)
21–24, ^a % (n)	59 (83)	59 (60)	65 (44)	60 (187)
Male, % (n)	71 (100)	75 (77)	69 (47)	72 (224)
Gay/bisexual (male only), % (n)	88 (87)	95 (72)	78 (36)	88 (195)
Ethnicity,** % (n)				
African American	33 (46)	22 (22)	22 (15)	27 (83)
Latino	32 (45)	46 (47)	34 (23)	37 (115)
White	18 (25)	12 (12)	32 (22)	19 (59)
Other	17 (24)	21 (21)	12 (8)	17 (53)
City,** % (n)				
Los Angeles	36 (50)	49 (50)	38 (26)	41 (126)
New York	37 (52)	13 (13)	38 (26)	29 (91)
San Francisco	12 (17)	21 (21)	16 (11)	16 (49)
Miami	15 (21)	18 (18)	7 (5)	14 (44)
Diagnostic status, % (n)				
Asymptomatic	57 (77)	61 (60)	62 (41)	59 (178)
Symptomatic	35 (47)	29 (28)	29 (19)	31 (94)
AIDS	9 (12)	10 (10)	9 (6)	9 (28)
T-cell count	499.0	468.1	474.9	483.4
Health-related issues				
No. of medical care contacts	21.1	19.0	21.8	20.5
No. of appointments missed	1.1	0.8	1.4	1.1
No. of positive lifestyle changes	4.8	5.0	4.9	4.9
No. of physical health symptoms	9.8	10.0	8.8	9.6
Mean physical health distress score	1.0	1.0	0.9	1.0
Coping				
Social support*	2.7	2.4	2.3	2.6
Positive action	3.4	3.4	3.3	3.3
Sexual behavior				
No sexual-risk pattern, % (n)	73 (102)	67 (68)	74 (50)	71 (220)
No. of sexual partners	3.1	2.6	2.6	2.8
No. of HIV-negative partners	4.9	2.2	2.2	3.4
No. of HIV-positive partners	0.4	0.5	0.4	0.4
Disclosed serostatus to sexual partners, %	53.5	54.0	54.3	53.8
Unprotected sex acts, %	11.3	12.6	7.2	10.8
Brief Symptom Inventory score	0.9	0.9	0.9	0.9
Substance use				
Abstains from alcohol and drugs, % (n)	24 (34)	22 (22)	19 (13)	22 (69)
Alcohol abstinent, % (n)	37 (52)	30 (31)	29 (20)	33 (103)
Drug abstinent, % (n)	44 (61)	48 (49)	41 (28)	45 (138)
Alcohol/marijuana use, % (n)	72 (101)	75 (77)	79 (54)	75 (232)
Marijuana use only, % (n)	46 (65)	43 (44)	50 (34)	46 (143)
Hard drug use, % (n)	35 (49)	30 (31)	32 (22)	33 (102)
Weighted index	69.6	36.8	33.5	50.9
No. of drugs used	1.1	0.9	1.1	1.0
Injection drug use,* % (n)	12 (17)	4 (4)	4 (3)	8 (24)

^aThere was 1 24-year-old youth living with HIV.

* $P < .05$; ** $P < .01$.

Among females, the number of positive lifestyle changes was significantly higher among intervention attendees than among control subjects (relative effect size [RES]=45.9%; $P=.003$) and intervention nonattendees (RES=35.4%; $P=.016$).

The positive action coping subscale score was significantly higher for females who were intervention attendees than for females in the control condition (RES=17.6%; $P=.029$). For both sexes, the social support coping score was significantly higher among intervention atten-

dees than among control subjects (RES=10.8%; $P=.04$) and intervention nonattendees (RES=16.8%; $P=.006$).

Module 2: “Act Safe”

Overall, only about 30% of HIV-infected youths reported having any sexual partners at the 15-month assessment. Compared with nonattendees, intervention attendees reported significantly fewer sexual partners (RES=51.5%; $P=.033$) and fewer

HIV-negative sexual partners (RES=54.3%; $P=.035$). Intervention attendees had a lower percentage of unprotected sexual risk acts than control subjects (RES=82.1%; $P=.013$) and intervention nonattendees (RES=74.0%; $P=.075$). There was no significant difference in disclosure of serostatus to sexual partners.

Comparing intervention attendees and nonattendees, there were significant reductions in the weighted substance use index (RES=49.7%; $P=.024$), the prevalence of alcohol or marijuana use (RES=25.7%; $P=.045$), and the

TABLE 2—Intervention Effects Based on Comparisons Among Intervention Attendees, Controls, and Intervention Nonattendees

	Intervention Attendees	Controls	Intervention Nonattendees	RES, Attendees vs Controls
Module 1 (“Stay Healthy”)				
	(n=129)	(n=76)	(n=52)	
Index of no. of medical care contacts	22.1	24.1	23.9	-8.2
No. of appointments missed	1.1	0.5	1.4	101.9
T-cell count	416.5	408.1	509.1 ^{b**}	2.1
Positive lifestyle changes (females)	6.0	4.1 ^{a***}	4.5 ^{b**}	45.9
No. of physical health symptoms	8.4	8.7	9.1	-3.1
Mean physical health distress score	0.8	0.9	0.9	-7.7
Brief Symptom Inventory score	0.7	0.7	0.8	2.8
Positive action (females)	3.4	2.9 ^{a**}	3.5	17.6
Social support (males and females)	2.6	2.3 ^{a**}	2.2 ^{b***}	10.8
Module 2 (“Act Safe”)				
	(n=80)	(n=30)	(n=44)	
Sexual behavior				
No sexual-risk pattern, %	80	67 ^{a**}	75	19.4
No. of sexual partners	1.7	3.0	3.4 ^{b**}	-45.0
No. of HIV-negative partners	1.4	2.9	3.1 ^{b**}	-50.0
No. of HIV-positive partners	0.2	0.2	0.2	15.0
Disclosed serostatus to sexual partners, %	64.2	55.6	54.8	15.4
Unprotected sex acts, %	2.8	15.5 ^{a**}	10.6 ^{b*}	82.1
Substance use				
Alcohol/marijuana, %	63	67	84 ^{b**}	-6.0
Hard drugs, %	21	27	39 ^{b*}	-22.2
Weighted index	20.2	29.2	40.2 ^{b**}	-30.8
No. of drugs	1.3	1.4	1.6	-6.3
Brief Symptom Inventory score	0.8	0.8	0.9	-1.2

Note. RES=relative effect size, defined as $100\% \times [(attendee's\ outcome - control\ outcome) / control\ outcome]$. Adjusted means are different owing to different analytic modules.

^aIntervention vs control.

^bIntervention attendees vs intervention nonattendees.

* $P < .10$; ** $P < .05$; *** $P < .01$.

use of hard drugs (RES=45.0%; $P=.097$). There were no significant differences between conditions in the number of drugs used or in emotional distress. Fewer than 5% of YLH reported contact with substance abuse treatment facilities across intervention conditions at any assessment; no changes were expected or observed on these measures because of the low base rates.

Discussion

Continued risk among HIV-positive persons has been well documented^{5,27,28}; this is one of the first studies of a prevention program with HIV-infected youths. The efficacy of this program appears to be similar to that of preventive interventions for seronegative persons.²⁹ At a cost of \$513 per youth, the “Act Safe” module resulted in a 50% reduction in the number of HIV-negative partners, an 82% decrease in the number of unprotected sex acts, and a 31% reduction in a weighted index of drug use. The “Stay Healthy” module (delivery cost of

\$467 per youth) focused on changing health behavior; however, fewer benefits were demonstrated. At baseline, 58% of HIV-infected youths were highly satisfied with their physician’s competence and 68% reported high levels of assertiveness, providing little opportunity for improvement.³⁰ Females in the “Stay Healthy” module changed health habits and increased their active coping styles. Both males and females increased their social support coping styles. Improvements in health behaviors have become increasingly important since the introduction of highly active antiretroviral therapy.^{11,14} Therefore, any future health promotion interventions must also focus on issues of medication adherence, as well as enhancing healthy lifestyles and assertiveness with care providers.

It is important to note that the behavioral changes were specific to the content of the intervention sessions in each module; for example, the “Stay Healthy” module did not affect sexual risk, even though health behaviors did change. The “Act Safe” module changed substance use and sexual risk, but no further

changes occurred in health acts. We also did not find a dose effect, which is not surprising, given the high attendance rate among intervention attendees.

The sample recruited for the study was relatively large, was recruited from 9 sites in 4 AIDS epicenters, matched the sociodemographic profile of HIV-infected youths in the Centers for Disease Control and Prevention’s national AIDS and HIV case data,² and demonstrated expected developmental patterns (e.g., risk acts increased with age; test-retest correlations on each measure increased with age). Although biological markers would have been desirable to confirm youths’ self-reports, these measures were not available at the time this study was initiated. Substantial evidence confirms the reliability and validity of self-reports of HIV-related risk acts.³¹

Over time, most HIV-infected youths engaged in exemplary health behaviors and low rates of transmission behavior. While their lifetime patterns were very risky (51% had had more than 20 sexual partners, 27% had bartered sex, 87% had used hard drugs, and 16% had injected drugs), only 22% of youths reported

engaging in unprotected sex in the 3 months before the baseline assessment, most disclosed their serostatus to all sexual partners, and only about half used drugs (mainly marijuana).³⁰ Receiving ongoing health care may account for relatively low levels of risk. Yet, a recent meta-analysis of the effect of HIV testing³² suggests that early detection alone may be a substantial preventive intervention. Not all HIV-infected youths need preventive interventions; HIV providers may need to screen for ongoing risk before delivering preventive interventions.

However, the mode of delivering preventive interventions to HIV-infected youths must be reexamined, as 27% did not attend even 1 intervention session. The youths reported liking and trusting the small-group format. Yet, scheduling difficulties, fears of stigmatization in a group setting, and slow accrual of HIV-infected youths led to fewer attending the intervention. Small groups also are not feasible in rural communities or for youths selected according to sex or language use; recruitment would be too slow. Alternative intervention strategies need to be evaluated (e.g., individual sessions, Internet-based or telephone groups). □

Contributors

M. J. Rotheram-Borus was the principal investigator on the project; she designed the study and wrote the first draft of the manuscript. M. B. Lee provided data analysis and wrote the Methods section of the manuscript. D. A. Murphy designed the assessment tools and edited subsequent drafts of the manuscript. D. Futterman worked on study design and implementation. N. Duan provided data support, methodologic review, and help with the writing and structure of the manuscript. J. M. Birnbaum and M. Lightfoot worked on the project and were involved in implementation of the intervention, data collection, and manuscript development. The Teens Linked to Care Consortium was involved in data collection and project implementation.

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The study was approved by the UCLA Human Subjects Protection Committee.

Members of the Teens Linked to Care Consortium are Timothy R. Cline, PhD, Ying-Ying Lin, MS, Dallas Swendeman, BA, Whitney Wright, CSW, and Michael Kennedy, MFCC (Larkin Street Youth Center, San Francisco, Calif).

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Improving the quality of life among young people living with HIV

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Abstract

A three-module intervention was designed to address the multiple needs of young persons living with HIV (YPLH): (1) Staying Healthy, (2) Acting Safe, and (3) Being Together. YPLH from three cities were assigned by small cohort to either an Immediate Intervention Condition or a Control Condition. Building on the positive effects of the Staying Healthy and Acting Safe Modules, this paper reports the effects of the Being Together Module, an eight-session cognitive-behavioral intervention aimed at improving YPLHs quality of life. The YPLH ($n = 104$) were aged 14–23 ($M = 21.03$); 73% were male; most were Latino (43%) or African American (24%). YPLH in the Immediate Intervention Condition were significantly less emotionally distressed on multiple indices than those in the Control Condition, and those who attended the intervention showed decreasing emotional distress even when controlling for HIV symptomatology. HIV preventive interventions must promote emotional well-being, as well as reduce risk acts and promote health behaviors. © 2001 Elsevier Science Ltd. All rights reserved.

Keywords: HIV; Quality of life; Young people

1. Introduction

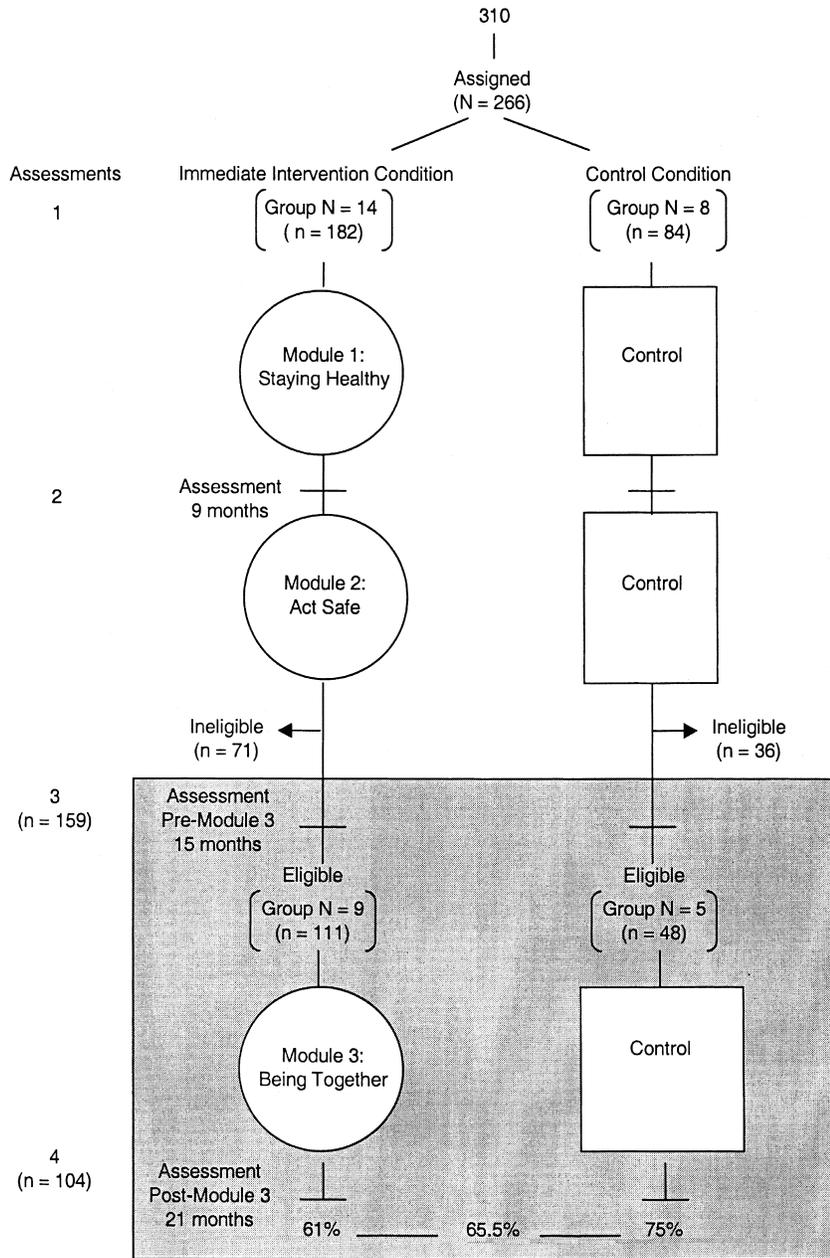
The World Health Organization and The Center for Disease Control estimate that 50% of all HIV infections occur among young people aged 15–24 years old (UNAIDS, 1998; CDC, 1999). It is estimated that nationally there are over 110,000 young people living with HIV (YPLH) (Rotheram-Borus, O’Keefe, Kracker & Foo, 2000). As a result of highly active antiretroviral therapy (HAART), the survival trajectory for YPLH has been extended (CDC, 1998), resulting in the transition of HIV from a debilitating terminal illness to a more manageable chronic illness. Given the transition in the course of disease, quality-of-life (QOL) issues become more salient. Quality of life may play a crucial role in influencing positive health behaviors and reducing or eliminating risk behaviors. Yet, little is known about the QOL of YPLH. The goal of this article is to examine the results from an intervention module, Being Together, aimed at improving QOL among YPLH.

Having a satisfying QOL is only one of the challenges facing YPLH. Initial challenges for YPLH are to acquire health care, follow medical regimens (now including HAART medications), and reduce transmission behaviors.

To address these issues, a three-module intervention was designed (Rotheram-Borus & Miller, 1998) and delivered to YPLH, as outlined in Fig. 1. The goal for each module was to attempt to change a different behavioral outcome: (1) Staying Healthy (targeted health care utilization and health behaviors); (2) Acting Safe (addressed transmission acts); and (3) Being Together (aimed at improving QOL). Similar to almost all successful interventions identified in the NIH Consensus Development Conference (1997), this intervention was delivered in small groups and used cognitive-behavioral strategies to change behaviors. Each module of the intervention was based on the social action model (Ewart, 1991), which emphasizes how contextual factors influence the individual’s ability to emotionally respond, solve problems, and act effectively in stressful situations. For example, YPLHs social relationships (e.g. with their doctors for health outcomes and with their sexual partners for transmission acts) are critical contextual features that must be addressed to change health and transmission behaviors. Setting mood is additional contextual features of behavior change addressed in each module.

The evaluation of the first two modules was summarized in a previous report (Rotheram-Borus et al., 2000, in press). The first module, Staying Healthy, addressed YPLHs motivation for self-preservation by encouraging positive health behaviors. Compared to the Control Condition, YPLH who

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Note: Shaded area represents study conditions and assessments for this report.

Fig. 1. Design of the trial indicating the number of YPLH assessed at baseline, prior to, and subsequent to delivery on Module 3.

attended the Staying Healthy Module increased positive coping styles, and the females improved health habits and health outcomes 3 months following the module. Once health behaviors had been improved, the public health agenda was addressed by trying to reduce YPLHs substance-use and risky sexual behaviors in Module 2 (Acting Safe). YPLH who attended the intervention had 52% fewer sexual partners, 54% fewer seronegative sexual partners, 82% fewer unprotected sexual risk acts, and 31% less substance use on a weighted index 3 months later,

compared with YPLH in the Control Condition. Thus, the first two modules of this intervention were successful in addressing health care, illicit drug use, and sexual transmission behavior issues (Rotheram-Borus et al., 2000, in press).

The third and final module of the intervention, Being Together, focused on improving the overall QOL among YPLH, and this paper summarizes these outcomes. Studies of HIV-infected adults have demonstrated the efficacy of small-group interventions in improving individuals' emotional and social functioning, as well as sense of

well-being (Kelly et al., 1993). A good QOL is of primary importance to those with a chronic or terminal illness because it makes positive behaviors salient and maintains motivation (Lawton, 1999). The benefits of maintaining a healthy lifestyle must be experienced daily or else there is reduced motivation for self-preservation. A positive QOL motivates individuals to sustain healthy behaviors over time.

The importance of QOL was recognized over four decades ago when Karnofsky, Abelmann, Craver and Burchenal (1948) developed a measure to assess quality of functioning. Almost concurrently, the World Health Organization (WHO) expanded its definition of health to include mental and social well-being (1947). Quality of life is a rich construct that can be operationalized in a variety of ways. Among persons living with HIV, QOL is typically measured, and was assessed in this study, with scales that ascertain four core areas: (1) physical health or physical health-related distress; (2) physical functioning; (3) energy/vitality; and (4) mental health or emotional well-being (Cohen, Hassan, Lapointe & Mount, 1996; Cunningham, Bozzette, Hays, Kanouse & Shapiro, 1995; Holmes & Shea, 1997; Lenderking, Testa, Katzenstein & Hammer, 1997; Lubeck & Fries, 1997; Piette, Wachtel, Mor, & Mayer, 1995).

Undoubtedly, illness severity is the strongest indicator of QOL among adult persons living with HIV (e.g. Lenderking et al., 1997; Smith et al., 1996; Sowell et al., 1997). Aside from illness severity, the QOL among persons living with HIV has been found to be a function of several sociodemographic factors and risky lifestyle histories. Women living with HIV appear to experience a lower level of QOL than men living with HIV (Lenderking et al., 1997). Among adult persons living with HIV, poor QOL has been associated with low income, older age, unemployment, stigma, fatalism, injection drug-use history, and low satisfaction with social support (Smith et al., 1996; Sowell et al., 1997; Swindells et al., 1999). We could not identify published studies that specifically address factors related to QOL among YPLH. Building on previous literature, Module 3 of the intervention was designed to improve QOL.

A frequently cited correlate of QOL among persons living with HIV is coping style (Friedland, Renwick & McColl, 1996; Hays et al., 1995; Leiberich et al., 1997; Lutgendorf, Antoni, Schneiderman & Fletcher, 1994; Renwick & Friedland, 1996; Swindells et al., 1999). For example, emotion-oriented coping has been shown to be negatively associated with QOL among persons living with HIV (Friedland et al., 1996). Lutgendorf et al. (1994) reported that QOL among persons living with HIV is positively associated with active coping, use of more functional appraisals, and decreased use of denial/avoidance coping. Leiberich et al. (1997) found evasive-regressive coping among persons living with HIV to be associated with low QOL and high emotional distress. Therefore, as a secondary outcome, we hypothesized that participation in Module 3 would influence coping style because this module addressed coping strategies for reducing negative feelings.

2. Methods

2.1. Participants and assignment

2.1.1. Initial sample

The study was conducted in eight adolescent clinical care sites in Los Angeles, New York, and San Francisco. The clinical sites were hospital-based adolescent medical clinics or community-based agencies that draw clients from multiple sources, including advocacy groups and advertisements. From these sites, 302 YPLH were recruited with informed consent. Parental consent was obtained if the YPLH was under age 18 and if the parents were available (e.g. the YPLH was not homeless) and knew the youth's HIV status. Each YPLH was paid \$20–25 to participate in a 2.5-h interview at the time of recruitment.

We reassessed the recruited YPLH approximately 3 months later. At this time, 36 YPLH were too sick to participate or were lost to follow-up. Thus, 266 YPLH were available to be assigned to the Immediate Intervention and the Control conditions, 126 from Los Angeles (two sites), 91 from New York (five sites), and 49 from San Francisco (one site).

YPLH were assigned to the Immediate Intervention or Control conditions in small cohorts of about 15 YPLH each. The number of YPLH in each cohort ranged from 4 to 20; all cohorts started at a minimum of 10 YPLH, but some YPLH were lost before assignment took place. The YPLH recruited were held in a waiting state until a sufficient number were recruited from the same site to form a cohort, a process usually taking several months. We assigned alternating cohorts within each site to the Immediate Intervention and Control conditions. To gain support for the program from the clinical staff, each site started with a cohort in the Immediate Intervention Condition; the next cohort was assigned to the Control Condition, etc. In six of our eight sites, we had an odd number of cohorts. Thus, the last cohort was assigned to the Immediate Intervention Condition. Therefore, as shown in Fig. 1, across the eight sites there were 14 cohorts in the Immediate Intervention Condition ($n = 182$; 13 per cohort, on average) and eight cohorts in the Control Condition ($n = 84$; 11 per cohort, on average).

Since sequential cohorts of YPLH were assigned to the intervention conditions, this design could result in a bias in the estimated intervention effect. If there was a systematic trend in the participants recruited, for example, the participants who were recruited early, and thus assigned to the Immediate Intervention Condition, may have engaged in more risk behaviors than those recruited later. Therefore, we used logistic regression to assess the presence of such time trends, regressing order of entry into the study on each index of risk behaviors collected at the baseline interview. No significant time trend was found in this analysis.

Among YPLH assigned to the Immediate Intervention and Control conditions ($n = 266$), most were male (79%); gay or bisexual males accounted for 69% of participating

Table 1

Sociodemographic characteristics at baseline of those who were evaluated prior to and following the module 3 intervention, those lost to follow-up, and those ineligible for participation (* $P < 0.05$)

	Evaluated ($n = 104$) %	Lost ($n = 55$) %	Ineligible ($n = 107$) %
Male*	73	93	77
Gay/Bisexual (Male only)	93	80	91
Lesbian (Female only)	18	0	13
Ethnicity			
African American	26	11	30
Latino	42	42	36
White	18	31	19
Other	13	16	16
Mean Baseline Age (in years) (SD)	21.03 (2.05)	21.44 (1.70)	20.67 (1.95)
High School Graduate/GED	63	72	61
City*			
Los Angeles	49	58	40
New York	36	18	41
San Francisco	15	24	19
HIV Symptomatic	30	47	42
Recent Unprotected Intercourse	20	20	17
Drugs/Alcohol Abstinence	20	15	20
No. Outpatient Visits (visits per subject)	5.20 (4.59)	5.46 (4.53)	6.13 (5.04)

YPLH. Participant age ranged from 13 to 24 years ($M = 20.96$, $SD = 2.1$); females were younger than males by about 1.2 years ($P < 0.0005$). Most YPLH belonged to ethnic minority groups (79%), and 64% had graduated from high school or had their GED. On average, YPLH had tested seropositive for HIV 2.1 years before they were recruited ($SD = 2.1$; median = 1.4 years).

2.1.2. Module 3 sub-sample

It took longer to recruit the YPLH than anticipated and, as a result, the funding ended before all YPLH completed all modules. It was not possible to extend funding because ethical considerations required that all YPLH had to be provided with the intervention, including those in the Control Condition. There were 159 YPLH who were recruited with sufficient time for evaluation of Module 3 (shaded area of Fig. 1); 55 were lost to follow-up (almost all during the delivery of Module 1). Thus, pre- and post-assessments were conducted with 104 YPLH for Module 3. As shown, 66% (104/159) of the original cohort were assessed for Module 3: 61% of those eligible from the Immediate Intervention Condition and 75% of those eligible from the Control Condition.

Table 1 presents baseline comparisons for the 104 YPLH for whom pre- and post-assessments were conducted, the ineligible YPLH ($n = 107$) who were recruited too late to be included in the assessment of Module 3, and the YPLH who were lost during the first 6 months of the study (i.e. during the delivery of Module 1; $n = 55$). As shown, the three groups differed in only two ways: more heterosexual males were lost to follow-up, and Los Angeles lost more YPLH compared to other sites. The analyses of the intervention effects controlled for these two factors.

As also shown in Table 1, most YPLH eligible for

Module 3 were gay or bisexual males who self-identified as African-American or Latino. More than half were high school graduates (or GED equivalent), most lived in Los Angeles or New York, and their mean age was 21 years ($SD = 2.05$). Nearly one third reported symptoms of HIV in their lifetime, but almost none had physical symptoms concurrent with the intervention. One out of five YPLH had recently (within the past 3 months) engaged in unprotected anal or vaginal intercourse, and a similar proportion had abstained from drugs and alcohol. In addition, YPLH had recently made five outpatient medical visits on average.

2.2. Intervention

Table 2 summarizes the content of each intervention module. Prior to the delivery of Module 3, all participants in the Intervention Condition received Modules 1 and 2 of the intervention. Therefore, the evaluation of Module 3 reflects the impact of Module 3, given the delivery of the previous two modules. The eight sessions of the Being Together Module emphasized how YPLH could increase their life satisfaction and emotional strength by: (1) identifying a basic set of values that define a personal identity as a person living with HIV, in particular distancing themselves from a self-destructive sense of self; (2) reducing negative emotional reactions (pain, loss, and discontent) in response to living with their serostatus; (3) increasing perceptions of personal control; (4) reducing self-destructive motivations, particularly for substance use; and (5) living fully and joyously in the present moment. In these eight sessions, YPLH learned how to develop an awareness of every moment in life through meditation. Each session of the intervention had a basic structure as follows: (1) review successes and goals from the previous session; (2) present new content; (3) set goals for the coming week; and (4)

Table 2
Content of intervention sessions^a

Session	Content
	Module 1: Staying Healthy
1	Attitudes toward living with HIV
2	Exploring future goals
3	Disclosure of status
4	Coping with stigma
5	Staying healthy
6	Drug and alcohol use
7	Changing substance abuse
8	Preventing re-infection
9	Staying calm
10	Attending health care appointments
11	Taking prescribed medications
12	Participating in medical care decisions
	Module 2: Act Safe
1	Protecting yourself and your partner
2	Selecting protection methods and sex acts
3	Disclosing your serostatus to your partner
4	Getting a partner to accept using condoms
5	Refusing unprotected sex
6	Establishing the commitment to be drug-free
7	Stopping drug and alcohol thoughts
8	Avoiding external triggers
9	Avoiding internal triggers
10	Handling anxiety and anger to reduce drug use
11	Handling drugs, alcohol, and sex
	Module 3: Being Together
1	How can I have a better quality of life?
2	How can I reduce negative feelings?
3	Who am I?
4	Is what I see the real thing?
5	What direction should I follow?
6	How can I be a good person?
7	How can I get wise?
8	How can I care about others?

identify positive experiences during the session. While YPLH varied in age from 14 to 23 years, the content and structure of the module were similar for all YPLH. Because the YPLH had initiated high risk acts at early ages, the intervention issues were very similar across age, and most participants were older adolescents (i.e. over age 16).

The intervention was delivered in small-group settings by facilitators trained specifically for this project. Facilitators were ethnically diverse male and female co-leader pairs. They received intensive training from teams of experienced cognitive-behavioral intervention researchers. The training included reviewing the study's theoretical orientation, the intervention manual, and a videotape of model sessions, as well conducting practice sessions. Actual group sessions were videotaped and rated for content delivery. Participants received \$10 for the first intervention session they attended. For each subsequent session attended, the incentive increased cumulatively by \$2 (\$12 for the second session, \$14 for the third session, etc.). See Rotheram-Borus et al. (2000, in press), for full methodological details of the intervention.

Table 3 summarizes the comparisons of background factors at baseline among three subgroups of YPLH based on their Module 3 intervention status: Intervention Attended (those assigned to the Immediate Intervention Condition who attended at least one session; $n = 42$), Control ($n = 36$), and Intervention Non-Attended (those assigned to the Immediate Intervention Condition who did not attend any sessions; $n = 26$). There were no statistically significant background differences between YPLH in the three conditions. Among YPLH assigned to the intervention, 62% ($n = 42$) attended at least one session. Among those who attended intervention sessions, mean attendance at Module 3 was 5.33 sessions ($SD = 2.58$, range = 1–8), indicating that 67% of the sessions were attended.

2.3. Assessments

Assessments were conducted at four points for YPLH in both conditions: (1) prior to any intervention; (2) 3 months following the delivery of Module 1; (3) 3 months following the delivery of Module 2 and prior to Module 3; and (4) 3 months following the delivery of Module 3. This report focuses on differences in YPLH from the third and fourth assessment points, as shown in Fig. 1.

Data were collected by trained, ethnically diverse interviewers using assessments programmed on laptop computers. Training for the interviewers included: reviewing all questions and role playing each question in the interview schedule, discussing hypothetical situations in-depth, reviewing intensively the written interviewer's guide created for this study, adhering to the crisis protocol, reporting physical or sexual abuse, using laptop computers, and making referrals. Different staff were used for the interviews than for the intervention delivery. Each interviewer received weekly individual supervision, including feedback from the QA review of their audiotaped interviews. All interviews were audiotaped, and about 10% were randomly monitored for QA. Assessments of appropriate referrals for crisis-related behaviors (suicide, health problems), clarification of ambiguous responses, and correct reading of transition statements indicated that interviewers had met interviewer criteria on 91% of the occasions, with a range of 82–100% for individual interviewer's accuracy.

2.3.1. Primary outcome: quality of life

The first three QOL measures were items from the Medical Outcome Study SF-36 instrument (Ware & Sherbourne, 1992). First, a subjective assessment of poor health was obtained by asking, 'In general, would you say your health is: excellent (1), very good (2), good (3), fair (4), or poor (5)?' Second, YPLH were asked how much they were physically limited by performing 10 activities of daily living, such as lifting objects, climbing stairs, or bathing and dressing (Ware & Sherbourne, 1992). Responses ranged from 'limited a lot (1)' to 'not limited at all (3)' ($\alpha = 0.94$). Third, YPLH were asked to rate their energy/vitality level

Table 3
Baseline characteristics for module 3

	Intervention attended (n = 42) %	Control (n = 36) %	Intervention non-attended (n = 26) %
Male	81	61	77
Gay/Bisexual (Male only)	91	95	95
Lesbian (Female only)	13	21	17
Ethnicity			
African American	33	25	15
Latino	38	44	46
White	21	11	23
Other	7	19	15
Mean Baseline Age (in years) (SD)	21.26 (1.68)	20.67 (2.51)	21.15 (1.89)
High School Graduate/GED	73	53	60
City			
Los Angeles	50	44	54
New York	38	36	31
San Francisco	12	19	15
HIV Symptomatic	34	26	28

on a nine-item scale (Ware & Sherbourne, 1992) ($\alpha = 0.86$), which assessed the amount of time they felt full of energy, nervous, worn out, etc. Responses ranged from ‘all of the time (1)’ to ‘none of the time (6)’.

The fourth aspect of QOL (mental health) was assessed by measuring symptoms of emotional distress with the Brief Symptom Inventory (BSI; Derogatis, 1993), which assesses the degree to which persons are bothered by mental health symptoms [scored 0 (‘not at all’) to 4 (‘extremely’)]. A global estimate of emotional distress was obtained with the total 53-item scale ($\alpha = 0.96$), and the nine primary symptom dimensions of the BSI were disaggregated to measure specific symptomatology: somatization (seven items, $\alpha = 0.81$), obsessive-compulsive disorder (six items, $\alpha = 0.88$), interpersonal sensitivity (four items, $\alpha = 0.68$), depression (six items, $\alpha = 0.83$), anxiety (six items, $\alpha = 0.83$), hostility (five items, $\alpha = 0.70$), phobic anxiety (five items, $\alpha = 0.82$), paranoid ideation (five items, $\alpha = 0.65$), and psychoticism (five items, $\alpha = 0.73$). Emotional distress was also measured with the 37-item Manifest Anxiety Scale (Reynolds & Richmond, 1985) ($\alpha = 0.91$). Symptoms of anxiety were measured as ‘present’ (2) or ‘absent’ (1). We examined sub-scales of the Manifest Anxiety Scale (physiological anxiety, worry/oversensitivity, and social concerns/concentration), but found no significant differences among the Intervention Attended, Intervention Non-Attended, and Control conditions. Therefore, these sub-scales are not presented. HIV symptomatology was assessed by asking YPLH at the post-Module 3 assessment, ‘Have you had HIV symptoms in the past 3 months?’

2.3.2. Secondary outcome: coping style

A modified version of the Dealing with Illness Inventory was used to assess coping style (Namir, Wolcott, Fawzy & Alumbaugh, 1987; Murphy, Rotheram-Borus & Marelich, 2000). YPLH were asked how often they used select coping

styles in the previous 3 months to help them deal with their HIV disease. Responses ranged from ‘never’ (1) to ‘always’ (5). Five of the factor-analyzed sub-scales are included in these analyses: positive action (11 items, $\alpha = 0.84$), self-destructive escape (six items, $\alpha = 0.72$), social support (five items, $\alpha = 0.76$), passive problem-solving (eight items, $\alpha = 0.81$), and non-disclosure (four items, $\alpha = 0.62$).

2.4. Data analysis

For this analysis, an intent-to-treat analysis was conducted by evaluating participants who were assessed at points 3 and 4 (see Fig. 1). Using pre-intervention scores, gender, and city as covariates, analysis of covariance (ANCOVA) was conducted to examine post-intervention scores between the Immediate Intervention and Control conditions. For intent-to-treat analyses, relative effect sizes were calculated with the following formula using data from ANCOVA results: $100\% \times [(Intervention\ Outcome - Control\ Outcome)/Control\ Outcome]$. After completing the intent-to-treat analysis, three-condition comparisons were made among the Intervention Attended, Control, and Intervention Non-Attended conditions to explore intervention effects that differentiated YPLH who were assigned to the intervention but did not attend from those who were assigned and did attend. Relative effect sizes for the three-condition comparisons were calculated with the following formula using data from ANCOVA results: $100\% \times [(Intervention\ Attended\ Outcome - Control\ Outcome)/Control\ Outcome]$. Means were adjusted to make them comparable with respect to baseline scores. Dose effects were assessed with Spearman correlation analyses: correlations number of intervention sessions attended and each study variable were examined. There were no significant Spearman correlations between the number of intervention sessions attended and outcome variables. Therefore, no dose effects are reported.

Longitudinal Ordinary Least Squares (OLS) multivariate

Table 4

Intervention effects based on intent-to-treat analyses and three-condition analyses (means adjusted for pre-intervention scores, gender and city). * $P < 0.05$, ** $P < 0.01$

	Immediate intervention ($n = 68$)	Control ($n = 36$)	Relative Effect Size ^a ($n = 42$)	Intervention Attended ($n = 36$)	Control ($n = 26$)	Intervention non-attended	Relative effect size (%) ^b
Poor Health Rating (1–5)	2.30	2.51	8.4%	2.47	2.51	2.00	1.6
Low Physical Limitation (1–3)	2.82	2.73	3.3%	2.82	2.73	2.81	3.3
Energy/Vitality (1–6)	4.08	4.02	1.5%	4.06	4.02	4.11	1.0
Brief Symptom Inventory (0–4)							
Global	0.48	0.80 ^{c**}	40.0%	0.43	0.80 ^{d**}	0.55 ^{c*}	46.3
Somatization	0.45	0.73 ^{c*}	38.4%	0.38	0.72 ^{d**}	0.54	47.2
Anxiety	0.33	0.79 ^{c**}	58.2%	0.29	0.79 ^{d**}	0.39 ^{c**}	63.3
Phobic Anxiety	0.34	0.71 ^{c**}	52.1%	0.25	0.71 ^{d**}	0.45	64.8
Manifest Anxiety (1–2)	1.33	1.38	3.6%	1.33	1.38	1.34	3.6
Coping (1–5)							
Non-Disclosure	2.16	2.48 ^{c*}	12.9%	2.03	2.47 ^{d**}	2.35	17.8

^a $100\% \times [(Intervention\ Outcome - Control\ Outcome) / Control\ Outcome]$.

^b $100\% \times [(Intervention\ Attended\ Outcome - Control\ Outcome) / Control\ Outcome]$.

^c Immediate Intervention vs. Control.

^d Intervention Attended vs. Control.

^e Control vs. Intervention Non-Attended.

regression analyses were used to elaborate relationships between intervention condition membership and change in QOL, to highlight the directions of associations and to assess the independent effects of coping. Change was computed by subtracting the value of a variable from its subsequent value. For OLS analyses, previous values of the dependent variable are controlled, so that coefficients for independent variables are effects on change in the dependent variable between two time points. In addition, previous values and change scores for coping are included as independent variables in the regression models. When a change score is included as a predictor of a subsequent outcome, previous scores represent the amount of the score that is stable between two time points, and the change score represents variation between the two time points. In all regression analyses, the comparison group for intervention attendance was Control Condition membership. For multivariate analyses, recent HIV symptomatology was controlled. By including HIV symptomatology as a covariate, it was possible to delineate effects of the intervention on QOL, independent of the effect of HIV symptoms on QOL. This type of control is important because presentation of somatic symptoms could be confounded by symptoms of HIV infection (Castellon, Hinkin, Wood & Yarema, 1998; Kalichman, Sikkema & Somlai, 1995).

3. Results

3.1. Intervention Effects

Table 4 presents post-intervention adjusted mean scores and relative effect sizes in the intent-to-treat analysis for the five domains of QOL for YPLH in the two intervention

conditions. Table 4 also summarizes the three-condition analysis comparing Intervention Attended, Intervention Non-Attended, and the Control conditions. As shown, results are similar between the intent-to-treat analysis and the three-condition analysis.

The pre-post differences on BSI global and subscale scores for the Intervention Condition decreased from 0.19 to 0.22; in contrast, the scale scores for the Control Condition increased from 0.04 to 0.19. After Module 3 implementation, YPLH assigned to the Immediate Intervention Condition had significantly lower global BSI scores than the Control Condition (relative effect size = 40.0%). On specific symptom scales, YPLH in the Intervention Attended Condition had significantly lower scores on somatization (relative effect size = 38.4%), anxiety (relative effect size = 58.2%), and phobic anxiety (relative effect size = 52.1%). There were no significant differences by intervention condition on the other six BSI subscales, and these scores are not shown in Table 4. Scores on the Manifest Anxiety scale did not differ significantly between the Immediate Intervention and Control conditions, or among the three conditions (Intervention Attended, Intervention Non-Attended, Control). Coping style was significantly different only for non-disclosure style of coping. Pre-post difference scores decreased 0.06 for the Intervention Condition (0.17 decrease for the Intervention Attended Condition) and increased 0.15 for the Control Condition. YPLH in the Intervention Attended Condition reported significantly lower levels of non-disclosure coping (i.e. refused to think about serostatus, hiding serostatus, etc.) than the Control Condition (relative effect size = 17.8%), as shown in Table 4. YPLH in the different conditions did not differ significantly on any of the other coping styles, and these scores are not shown in Table 4.

Table 5

Regression of post-module 3 global BSI, BSI-somatization, and BSI-phobic anxiety on intervention group status, HIV symptomatology, and change in non-disclosure coping ($n = 93$), * $P < 0.05$, ** $P < 0.01$

Independent variables	Global BSI			BSI Somatization			BSI-Phobic Anxiety		
	B	(SE)	β	B	(SE)	β	B	(SE)	β
Pre-Module 3 BSI	0.49	(0.07)	0.57**	0.38	(0.07)	0.44**	0.48	(0.07)	0.56**
Intervention Attended ^a	- 0.20	(0.09)	- 0.19*	- 0.31	(0.11)	- 0.27**	- 0.30	(0.12)	- 0.23*
Intervention Non-Attended ^a	- 0.09	(0.11)	- 0.08	- 0.09	(0.12)	- 0.07	- 0.13	(0.14)	- 0.10
HIV Symptoms in Past 3 Months (/no)	0.36	(0.13)	0.23**	0.61	(0.14)	0.36**	0.18	(0.16)	0.10
Pre-Module 3 Non-Disclosure Coping	0.10	(0.05)	0.19*	0.09	(0.05)	0.15	0.11	(0.06)	0.18*
Change in Non-Disclosure Coping	0.08	(0.06)	0.12	- 0.03	(0.07)	- 0.03	0.13	(0.08)	0.15
	$R^2 = 0.53$			$R^2 = 0.48$			$R^2 = 0.45$		
	$F(6,86) = 16.16^{**}$			$F(6,86) = 13.09^{**}$			$F(6,86) = 11.73^{**}$		

^a Reference group = Control condition.

There were no significant pre- and post-intervention mean differences among YPLH in either of the intervention conditions for subjective poor health, physical limitations, or energy/vitality level, which may be indicative of the relative healthiness of this cohort. That is, the absence of a significant intervention effect may have resulted from initially high levels of energy/vitality and low levels of physical limitation. For example, prior to implementation of Module 3, the mean level of physical limitation for all YPLH was 2.77 (SD = 0.42). Responses to this scale range from 1 to 3 (where 3 = *not at all physically limited*), clearly demonstrating that most YPLH were experiencing no limitations in their physical activity and that changes in physical limitation were constrained by ceiling effects. Similarly, ceiling effects on pre-intervention scores were found for energy/vitality ($M = 4.26$ (SD = 1.30), range = 1–6). These constrained pre-intervention scores, combined with the small sample size, may have made it difficult to detect a significant intervention effect.

3.1.1. Elaboration of intervention effects

Elaboration of the intervention effects was accomplished by introducing other select variables into OLS regression models for change in emotional distress. In the Elaboration Model, a focal relationship is expanded upon in an attempt to further explain or specify the relationship (Aneshensel, 1999; Rosenberg, 1968). The focal relationship may be weakened or bolstered by other factors or may remain unaffected. In either case, it has been made more meaningful.

Focal relationships between intervention group attendance and the QOL were elaborated by including covariates in longitudinal analyses of three of the emotional distress outcomes that differed significantly by intervention condition (global BSI, BSI-somatization, and BSI-phobic anxiety). HIV symptomatology was controlled to account for confounding effects of HIV-related health on emotional distress. Non-disclosure coping and change in non-disclosure coping were included as correlates because bivariate analyses revealed a significant positive association between this style of coping and the global BSI measure (Pearson $R = 0.21$, $P < 0.05$) and

because the Intervention Attended Condition differed significantly from the Control Condition on this measure, as discussed above. Demographic variables (age, gender, city, sexual orientation, ethnicity, and education) were controlled for in initial analyses, but none of these variables were independently associated with emotional distress and, therefore, are not included in the OLS models. In these analyses, the intervention effect is a measure of its independent effect on change in emotional distress over time, holding constant non-disclosure coping, change in non-disclosure coping, HIV symptomatology, and initial levels of emotional distress. The regression model for BSI-anxiety is not presented because change in BSI-anxiety was not independently associated with non-disclosure coping, change in non-disclosure coping, or HIV symptomatology.

Correlates of the global BSI measure of emotional distress, BSI-somatization, and BSI-phobic anxiety are shown in Table 5. Decrease in global emotional distress between the pre- and post-Module 3 assessments was a function of being in the Intervention Attended group. Increase in global emotional distress was a function of persisting high levels of emotional distress, Control Condition membership (as opposed to Intervention Attended membership), HIV symptomatology, and elevated levels of non-disclosure coping prior to Module 3. That is, YPLH in the Intervention Attended Condition were less likely to experience increasing emotional distress than YPLH in the Control Condition, who initially scored high on non-disclosure coping and emotional distress, and who experienced symptoms of HIV in the past 3 months. Independent variables in this model accounted for a large amount of variance in changing emotional distress, largely attributable to persisting levels of emotional distress.

Decreasing somatization was a function of being in the Intervention Attended group. Increasing somatization was a function of persisting levels of somatic symptoms, Control Condition membership (as opposed to Intervention Attended membership), and HIV symptomatology. The effect of HIV symptomatology was larger in magnitude than the Intervention Attended effect but established the independent influence

of the intervention on decreasing somatization, holding constant the effect of HIV-related health. Similar to the model for global emotional distress, independent variables in this model accounted for a large proportion of the variance in changing somatization, largely attributable to persisting somatization.

Decreasing phobic anxiety was associated with being in the Intervention Attended group. Increasing phobic anxiety was associated with persisting phobic anxiety, Control Condition membership (as opposed to Intervention Attended membership), and pre-Module 3 non-disclosure coping. HIV symptomatology was not independently associated with increasing phobic anxiety, and this model accounts for 45% of the variance in increasing phobic anxiety.

4. Discussion

The Being Together intervention module, which aimed to improve the QOL among YPLH, had a statistically significant influence on emotional distress, a key aspect of QOL. Compared to YPLH in the Control Condition, YPLH who attended the Being Together intervention reported significantly lower levels of global emotional distress, somatization, anxiety, and phobic anxiety, as measured by the BSI, with relative effect sizes ranging from 46.3 to 64.8%. BSI scores found among these YPLH were also lower than scores found in an adolescent nonpatient normative sample (Derogatis, 1993). In addition, intervention attendance was associated with decreasing emotional distress over time. These results demonstrate that the intervention was successful in providing YPLH with skills and affective response repertoires that improved their psychological health.

For this study, we examined how the intervention effect on emotional distress would be weakened or bolstered by controlling for HIV symptomatology. We found that the intervention influences YPLHs emotional distress, even when controlling for HIV symptoms in the past 3 months. This is an important finding in light of the fact that change in emotional distress, especially somatization, may have reflected HIV symptom experience. Standardized regression coefficients indicated that effect sizes for intervention attendance and HIV symptomatology were somewhat similar. In fact, the unstandardized effect size for intervention attendance fell within the 95% confidence interval of HIV symptomatology for both the global BSI measure and somatization. The focal relationship between intervention attendance and decreasing somatization was enhanced by controlling for HIV symptomatology, which did not independently influence change in phobic anxiety.

Non-disclosure coping independently affected global emotional distress and phobic anxiety. The relationships were positive, indicating that high and increasing levels of this style of coping were related to increasing emotional distress. These findings are consistent with previous research (Murphy et al., 2000), in which non-adaptive

coping was associated directly with increased anxiety and depression. Thus, in comparison to Control Condition membership, intervention attendance is related to decreasing emotional distress, taking into account unit change in non-disclosure coping. The magnitude of the intervention effect in all regression models was larger than that for non-disclosure coping, demonstrating the pervasive influence of the intervention in affecting YPLHs mental health.

The Being Together intervention module was associated with differences in only one coping style: non-disclosure coping. There was no significant interaction effect between intervention attendance and non-disclosure coping on any of the mental health outcomes. Further investigation is needed to identify how non-disclosure influences QOL.

The intervention may have been associated with somatic symptomatology because of the intervention's focus on developing meditation skills. Meditation is a widely used technique for stress management, as well as pain management and control (Gordon, Sobel & Tarazona, 1998; McCain et al., 1996; Vigne, 1997). Meditation may enable YPLH to learn to appraise their experience of HIV symptoms or other health problems in relation to the meanings they attach to bodily sensations, rather than to their awareness of underlying disease. By utilizing meditation techniques for exploring the self, and by learning how not to separate the self from pain and physical symptomatology, YPLH may be instilled with skills that allow them to endure discomfort or perceive lower levels of discomfort. Experiences of discomfort may, in turn, be manifested in terms of somatic symptoms.

Limitations of the study and the data analyzed and presented merit mention. Because of slow recruitment rates and clinician' concerns, we did not randomly assign individual YPLH to intervention conditions, which may pose a threat to internal validity. Examination of the socio-demographic, health, and transmission behaviors among the YPLH did not indicate a selection bias. We assessed a relatively large number of primary and secondary outcomes which increases the possibility that the significant intervention effects were due to chance. The small sample size may also have limited our ability to detect significant and important differences between groups of YPLH based on their intervention status (i.e. attended, non-attended, and control). For example, the three groups did not differ by gender, even though 81% of YPLH who attended the Being Together module were male and only 61% of YPLH in the control group were male. In addition, it was not possible to control for multiple other possible predictors of emotional distress in the longitudinal regression models because the sample size limited the number of independent variables that could be examined. In the longitudinal regression models, endogeneity of the change in coping score could have resulted in biased parameter estimates. However, there was no indication that a serious selection bias was operating and those factors that were associated with retention in the study (being male and in San Francisco or New York) were

controlled in all analysis. Although we treated change in coping as an independent variable, it is possible that it may have been influenced by other variables in the system and such endogeneity may have affected the results.

The changes found in association with attending this intervention module are going to become increasingly important as YPLH live longer with the success of highly active anti-retroviral therapies. A positive QOL provides motivation for survival and healthy behaviors among those with a chronic or terminal illness. By promoting positive states of emotional well-being, interventions that aim to improve QOL may also support the public health agenda by encouraging and supporting the maintenance of behaviors that reduce HIV transmission and drug-resistant viral mutation.

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Appendix B

Stakeholder's Checklist



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Stakeholder's Checklist

1. Assess the community to determine whether they will support the core elements of **TLC**.
2. Identify your stakeholders:
 - a. Your agency's Board of Directors/Executive Board.
 - b. Staff members from your agency who will have a role in the operation of the intervention:
 - Administrators who will obtain support.
 - Supervisors who will monitor the intervention.
 - Staff who will interact with participants at any level.
 - c. Local agencies from which you could recruit participants, facilitators or both:
 - Agencies offering support groups for people living with HIV/AIDS.
 - Health care providers and mental health professionals serving people living with HIV/AIDS.
 - Social service agencies reaching people living with HIV/AIDS.
 - Organizations of people living with HIV/AIDS and organizations which may have members who are living with HIV/AIDS.
 - d. Organizations which could provide assistance or other resources:
 - Merchants for incentives and refreshments.
 - Agencies, merchants, printers, publishers, broadcasters and others who can advertise the intervention.
 - Agencies that can provide a venue for the intervention.
 - Agencies that can provide child care.
 - Agencies that can provide transportation.
 - Agencies that can provide informed volunteers for your community advisory group to help tailor the intervention.
 - Other collaborating agencies to provide information for Resource Packets.
 - e. Agencies with which your agency needs to maintain good community or professional relations:
 - Local health department.
 - Local medical and mental health associations.

Stakeholder's Checklist - *continued*

- Your funding source(s).
 - Others.
3. Getting stakeholders informed, supportive and involved.
- a. Getting them informed about the intervention.
- Decide in advance what specific roles you want each stakeholder to play. Who will you ask to:
 - Provide financial support?
 - Refer people living with HIV/AIDS to the intervention?
 - Serve as an intervention facilitator?
 - Be a resource to which you can refer participants?
 - Join your community advisory group?
 - Help tailor the intervention for your target population?
 - Assist in advertising the intervention?
 - Provide a room in which the sessions can be held?
 - Supply refreshments for participants?
 - Donate small incentives or prizes for participants?
 - Speak supportively about **TLC** in conversations with their associates?
 - Send letters that tell stakeholders about **TLC**, its importance, that your agency will be making the intervention available, the specific role(s) you think that they might play in the success of the intervention, and invite them to learn more.
 - Call in two weeks and assess their interest. If they are interested, schedule a time to meet (e.g., one-on-one, lunch-and-learn at your agency with a group of other stakeholders, presentation at their agency for several of their staff or association members).
 - Hold the meeting, show the **TLC** marketing video if the setting and time allow, answer questions.
- b. Getting them supportive.
- Describe several specific roles they could play.
 - Emphasize the benefits of their involvement to themselves, their agency, the community and people living with HIV/AIDS, and answer questions.
 - Invite them to commit to supporting **TLC** by taking on one or more roles. Keep track of commitments.

c. Getting them involved.

- Soon after meeting, send a thank-you letter that specifies the role(s) to which they committed. If they did not commit, send a letter thanking them for their time and interest and ask them to keep the letter on file in case they reconsider later.
- Provide immediate and specific work assignments to people who committed to a role that is important to pre-implementation.
- For people who committed to roles that begin later in the process, provide progress updates and a projected time frame for their involvement.
- Hold periodic celebratory meetings for supporters to acknowledge the value of their contributions, update them on the intervention's progress and keep them engaged.



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Appendix C

CDC Information and Guidelines

- [The ABCs of Smart Behavior to Avoid or Reduce the Risk for HIV](#)
- [CDC Content and Review Guidelines for HIV Programs](#)
- [Male Latex Condoms and Sexually Transmitted Diseases](#)
- [CDC Statement on Nonoxynol-9 Spermicide Contraception Use-US \(1999\)](#)
- [CDC Statement for Study Results of Product Containing Nonoxynol-9 \(2000\)](#)



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The ABCs of Smart Behavior

To Avoid or Reduce the Risk for HIV

A Stands for abstinence.

B Stands for being faithful to a single sexual partner.

C Stands for using condoms consistently and correctly.



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CDC Content and Review Guidelines

for HIV Programs

Centers for Disease Control and Prevention

Revised Interim HIV Content Guidelines for AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments and Educational Sessions for CDC Assistance Programs

I. Basic Principles

Controlling the spread of HIV infection and the occurrence of AIDS requires the promotion of individual behaviors that eliminate or reduce the risk of acquiring and spreading the virus. Messages must be provided to the public that emphasize the ways by which individuals can protect themselves from acquiring the virus. These methods include abstinence from illegal use of IV drugs as well as from sexual intercourse except in a mutually monogamous relationship with an uninfected partner.

For those individuals who do not or cannot cease risky behavior, methods of reducing their risk of acquiring or spreading the virus must also be communicated. Such messages are often controversial. The principles contained in this document are intended to provide guidance for the development and use of HIV/AIDS-related educational materials developed or acquired in whole or in part using CDC HIV prevention funds and to require the establishment of at least one Program Review Panel by state and local health departments, to consider the appropriateness of messages designed to communicate with various groups. State and local health departments may, if they deem it appropriate, establish multiple Program Review Panels to consider the appropriateness of messages designed to communicate with various groups.

A. Written materials (e.g., pamphlets, brochures, curricula, fliers), audiovisual materials (e.g., motion pictures and videotapes), pictorials (e.g., posters and similar educational materials using photographs, slides, drawings or paintings) and marketing, advertising, Web site-based HIV/AIDS educational materials, questionnaires or survey instruments should use terms, descriptors or displays necessary for the intended audience to understand dangerous behaviors and explain practices that eliminate or reduce the risk of HIV transmission.

B. Written materials, audiovisual materials, pictorials and marketing, advertising, Web site-based HIV/AIDS educational materials, questionnaires or survey instruments should be reviewed by a Program Review Panel established by a state or local health department, consistent with the provisions of section 2500(b), (c) and (d) of the Public Health Service Act, 42 U.S.C. Section 300ee(b), (c) and (d), as follows:

SEC. 2500. USE OF FUNDS.

(b) Contents of Programs.--All programs of education and

information receiving funds under this title shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse and the benefits of abstaining from such activities.

(c) Limitation.--None of the funds appropriated to carry out this title may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.

(d) Construction.--Subsection (c) may not be construed to restrict the ability of an educational program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to or to transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

C. Educational sessions should not include activities in which attendees participate in sexually suggestive physical contact or actual sexual practices.

D. Program Review Panels must ensure that the title of materials developed and submitted for review reflects the content of the activity or program.

E. When HIV materials include a discussion of condoms, the materials must comply with Section 317P of the Public Health Service Act, 42 U.S.C. Section 247b-17, which states in pertinent part:

“educational materials . . . that are specifically designed to address STDs . . . shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address.”

II. Program Review Panel

Each recipient will be required to identify at least one Program Review Panel, established by a state or local health department from the jurisdiction of the recipient. These Program Review Panels will review and approve all written materials, pictorials, audiovisuals, marketing, advertising and Web site materials, questionnaires or survey instruments (except questionnaires or survey instruments previously reviewed by an Institutional Review Board--these questionnaires or survey instruments are limited to use in the designated research project). The requirement applies regardless of whether the applicant plans to conduct the total program activities or plans to have part of them conducted through other organization(s) and whether program activities involve creating unique materials or using/distributing modified or intact materials already developed by others. Materials developed by the U.S. Department of Health and Human Services do not need to be reviewed by a panel. Members of a Program Review Panel should understand how HIV is and is not transmitted and understand the epidemiology and extent of the HIV/AIDS problem in the local population and the specific audiences for which materials are intended.

A. The Program Review Panel will be guided by the CDC Basic Principles (see Section I above) in conducting such reviews. The panel is authorized to review materials only and is not empowered either to evaluate the proposal as a whole or to replace any internal review panel or procedure of the recipient organization or local governmental jurisdiction.

B. Applicants for CDC assistance will be required to include in their applications the following:

1. Identification of at least one panel, established by a state or local health department, of no less than five persons who represent a reasonable cross-section of the jurisdiction in which the program is based. Since Program Review Panels review materials for many intended audiences, no single intended audience shall dominate the composition of the Program Review Panel, except as provided in subsection d below.

In addition:

a. Panels that review materials intended for a specific audience should draw upon the expertise of individuals who can represent cultural sensitivities and language of the intended audience, either through representation on the panel or as consultants to the panels.

b. Panels must ensure that the title of materials developed and submitted for review reflect the content of the activity or program.

c. The composition of Program Review Panels must include an employee of a state or local health department with appropriate expertise in the area under consideration, who is designated by the health department to represent the department on the panel.

d. Panels reviewing materials intended for racial and ethnic minority populations must comply with the terms of a-c above. However, membership of the Program Review Panel may be drawn predominantly from such racial and ethnic populations.

2. A letter or memorandum to the applicant from the state or local health department, which includes:

a. Concurrence with this guidance and assurance that its provisions will be observed.

b. The identity of members of the Program Review Panel, including their names, occupations and any organizational affiliations that were considered in their selection for the panel.

C. When a cooperative agreement/grant is awarded and periodically thereafter, the recipient will:

1. Present for the assessment of the appropriately identified Program Review Panel(s) established by a state or local health department, copies of written materials, pictorials, audiovisuals and marketing, advertising, Web site HIV/AIDS educational materials, questionnaires and surveys proposed to be used. The Program Review Panel shall pay particular attention to ensure that none of the above materials violate the provisions of Sections 2500 and 317P of the Public Health Service Act.

2. Provide for assessment by the appropriately identified Program Review Panel(s) established by a state or local health department, the text, scripts or detailed descriptions for written materials, pictorials, audiovisuals and marketing, advertising and Web site materials that are under development.

3. Prior to expenditure of funds related to the ultimate program use of these materials, assure that its project files contain a statement(s) signed by the chairperson of the appropriately identified

Program Review Panel(s) established by a state or local health department, specifying the vote for approval or disapproval for each proposed item submitted to the panel.

4. Include a certification that accountable state or local health officials have independently reviewed written materials, pictorials, audiovisuals and marketing, advertising and Web site materials for compliance with Section 2500 and 317P of the Public Health Service Act and approved the use of such materials in their jurisdiction for directly and indirectly funded community-based organizations.

5. As required in the notice of grant award, provide to CDC in regular progress reports, signed statement(s) of the chairperson of the Program Review Panel(s) specifying the vote for approval or disapproval for each proposed item that is subject to this guidance.

D. CDC-funded organizations, which are national or regional (multi-state) in scope or that plan to distribute materials as described above to other organizations on a national or regional basis, must identify a single Program Review Panel to fulfill this requirement. Those guidelines identified in Sections I.A. through I.D. and II.A. through II.C. outlined above also apply. In addition, such national/regional panels must include, as a member, an employee of a state or local health department.

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For more information
CDC's National Prevention Information Network
800) 458-5231 or www.cdcnpin.org

CDC National STD/HIV Hotline
(800) 227-8922 or (800) 342-2437
En Español (800) 344-7432
www.cdc.gov/std

Fact Sheet for Public Health Personnel:

Male Latex Condoms and Sexually Transmitted Diseases

In June 2000, the National Institutes of Health (NIH), in collaboration with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the United States Agency for International Development (USAID), convened a workshop to evaluate the published evidence establishing the effectiveness of latex male condoms in preventing STDs, including HIV. A summary report from that workshop was completed in July 2001 (<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>). This fact sheet is based on the NIH workshop report and additional studies that were not reviewed in that report or were published subsequent to the workshop (see "Condom Effectiveness" for additional references). Most epidemiologic studies comparing rates of STD transmission between condom users and non-users focus on penile-vaginal intercourse.

Recommendations concerning the male latex condom and the prevention of sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), are based on information about how different STDs are transmitted, the physical properties of condoms, the anatomic coverage or protection that condoms provide, and epidemiologic studies of condom use and STD risk.

The surest way to avoid transmission of sexually transmitted diseases is to abstain from sexual intercourse, or to be in a long-term mutually monogamous relationship with a partner who has been tested and you know is uninfected.

For persons whose sexual behaviors place them at risk for STDs, correct and consistent use of the male latex condom can reduce the risk of STD transmission. However, no protective method is 100 percent effective, and condom use cannot guarantee absolute protection against any STD. Furthermore, condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV and other STDs. In order to achieve the protective effect of condoms, they must be used correctly and consistently. Incorrect use can lead to condom slippage or breakage, thus diminishing their protective effect. Inconsistent use, e.g., failure to use condoms with every act of intercourse, can lead to STD transmission because transmission can occur with a single act of intercourse.

While condom use has been associated with a lower risk of cervical cancer, the use of condoms should not be a substitute for routine screening with Pap smears to detect and prevent cervical cancer.

Sexually Transmitted Diseases, Including HIV

Sexually transmitted diseases, including HIV

Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS. In addition, correct and consistent use of latex condoms can reduce the risk of other sexually transmitted diseases (STDs), including discharge and genital ulcer diseases. While the effect of condoms in preventing human papillomavirus (HPV) infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.

There are two primary ways that STDs can be transmitted. Human immunodeficiency virus (HIV), as well as gonorrhea, chlamydia, and trichomoniasis – the discharge diseases – are transmitted when infected semen or vaginal fluids contact mucosal surfaces (e.g., the male urethra, the vagina or cervix). In contrast, genital ulcer diseases – genital herpes, syphilis, and chancroid – and human papillomavirus are primarily transmitted through contact with infected skin or mucosal surfaces.

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. Condoms can be expected to provide different levels of protection for various sexually transmitted diseases, depending on differences in how the diseases are transmitted. Because condoms block the discharge of semen or protect the male urethra against exposure to vaginal secretions, a greater level of protection is provided for the discharge diseases. A lesser degree of protection is provided for the genital ulcer diseases or HPV because these infections may be transmitted by exposure to areas, e.g., infected skin or mucosal surfaces, that are not covered or protected by the condom.

Epidemiologic studies seek to measure the protective effect of condoms by comparing rates of STDs between condom users and nonusers in real-life settings. Developing such measures of condom effectiveness is challenging. Because these studies involve private behaviors that investigators cannot observe directly, it is difficult to determine accurately whether an individual is a condom user or whether condoms are used consistently and correctly. Likewise, it can be difficult to determine the level of exposure to STDs among study participants. These problems are often compounded in studies that employ a “retrospective” design, e.g., studies that measure behaviors and risks in the past.

As a result, observed measures of condom effectiveness may be inaccurate. Most epidemiologic studies of STDs, other than HIV, are characterized by these methodological limitations, and thus, the results across them vary widely--ranging from demonstrating no protection to demonstrating substantial protection associated with condom use. This inconclusiveness of epidemiologic data about condom effectiveness indicates that more research is needed--not that latex condoms do not work. For HIV infection, unlike other STDs, a number of carefully conducted studies, employing more rigorous methods and measures, have demonstrated that consistent condom use is a highly effective means of preventing HIV transmission.

Another type of epidemiologic study involves examination of STD rates in populations rather than individuals. Such studies have demonstrated that when condom use increases within population groups, rates of STDs decline in these groups. Other studies have examined the relationship between condom use and the complications of sexually transmitted infections. For example, condom use has been associated with a decreased risk of cervical cancer – an HPV associated disease.

The following includes specific information for HIV, discharge diseases, genital ulcer diseases and human papillomavirus, including information on laboratory studies, the theoretical basis for protection and epidemiologic studies.

HIV / AIDS

HIV, the virus that causes AIDS

Latex condoms, when used consistently and correctly, are highly effective in preventing the sexual transmission of HIV, the virus that causes AIDS.

AIDS is, by far, the most deadly sexually transmitted disease, and considerably more scientific evidence exists regarding condom effectiveness for prevention of HIV infection than for other STDs. The body of research on the effectiveness of latex condoms in preventing sexual transmission of HIV is both comprehensive and conclusive. In fact, the ability of latex condoms to prevent transmission of HIV has been scientifically established in “real-life” studies of sexually active couples as well as in laboratory studies.

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. Latex condoms cover the penis and provide an effective barrier to exposure to secretions such as semen and vaginal fluids, blocking the pathway of sexual transmission of HIV infection.

Epidemiologic studies that are conducted in real-life settings, where one partner is infected with HIV and the other partner is not, demonstrate conclusively that the consistent use of latex condoms provides a high degree of protection.

Discharge Diseases, Including Gonorrhea, Chlamydia, and Trichomoniasis.

Discharge diseases, other than HIV

Latex condoms, when used consistently and correctly, can reduce the risk of transmission of gonorrhea, chlamydia, and trichomoniasis.

Gonorrhea, chlamydia, and trichomoniasis are termed discharge diseases because they are sexually transmitted by genital secretions, such as semen or vaginal fluids. HIV is also transmitted by genital secretions.

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. The physical properties of latex condoms protect against discharge diseases such as gonorrhea, chlamydia, and trichomoniasis, by providing a barrier to the genital secretions that transmit STD-causing organisms.

Epidemiologic studies that compare infection rates among condom users and nonusers provide evidence that latex condoms can protect against the transmission of chlamydia, gonorrhea and trichomoniasis. However, some other epidemiologic studies show little or no protection against these infections. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against the discharge diseases. More research is needed to assess the degree of protection latex condoms provide for discharge diseases, other than HIV.

Genital Ulcer Diseases and Human Papillomavirus

Genital ulcer diseases and HPV infections

Genital ulcer diseases and HPV infections can occur in both male and female genital areas that are covered or protected by a latex condom, as well as in areas that are not covered. Correct and consistent use of latex condoms can reduce the risk of genital herpes, syphilis, and chancroid only when the infected area or site of potential exposure is protected. While the effect of condoms in preventing human papillomavirus infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.

Genital ulcer diseases include genital herpes, syphilis, and chancroid. These diseases are transmitted primarily through “skin-to-skin” contact from sores/ulcers or infected skin that looks normal. HPV infections are transmitted through contact with infected genital skin or mucosal surfaces/fluids. Genital ulcer diseases and HPV infection can occur in male or female genital areas that are, or are not, covered (protected by the condom).

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. Protection against genital ulcer diseases and HPV depends on the site of the sore/ulcer or infection. Latex condoms can only protect against transmission when the ulcers or infections are in genital areas that are covered or protected by the condom. Thus, consistent and correct use of latex condoms would be expected to protect against transmission of genital ulcer diseases and HPV in some, but not all, instances.

Epidemiologic studies that compare infection rates among condom users and nonusers provide evidence that latex condoms can protect against the transmission of syphilis and genital herpes. However, some other epidemiologic studies show little or no protection. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against the genital ulcer diseases. No conclusive studies have specifically addressed the transmission of chancroid and condom use, although several studies have documented a reduced risk of genital ulcers in settings where chancroid is a leading cause of genital ulcers. More research is needed to assess the degree of protection latex condoms provide for the genital ulcer disease.

While some epidemiologic studies have demonstrated lower rates of HPV infection among condom users, most have not. It is particularly difficult to study the relationship between condom use and HPV infection because HPV infection is often intermittently detectable and because it is difficult to assess the frequency of either existing or new infections. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against HPV infection.

A number of studies, however, do show an association between condom use and a reduced risk of HPV-associated diseases, including genital warts, cervical dysplasia and cervical cancer. The reason for lower rates of cervical cancer among condom users observed in some studies is unknown. HPV infection is believed to be required, but not by itself sufficient, for cervical cancer to occur. Co-infections with other STDs may be a factor in increasing the likelihood that HPV infection will lead to cervical cancer. More research is needed to assess the degree of protection latex condoms provide for both HPV infection and HPV-associated disease, such as cervical cancer.

Department of Health and Human Services

For additional information on condom effectiveness, contact
CDC's National Prevention Information Network
(800) 458-5231 or www.cdcnpin.org

Nonoxynol-9 Spermicide Contraception Use—United States, 1999

MMWR, May 10, 2002 (Vol. 51, No. 18).

Most women in the United States with human immunodeficiency virus (HIV) become infected through sexual transmission and a woman's choice of contraception can affect her risk for HIV transmission during sexual contact with an infected partner. Most contraceptives do not protect against transmission of HIV and other sexually transmitted diseases (STDs) (1) and the use of some contraceptives containing nonoxynol-9 (N-9) might increase the risk for HIV sexual transmission. Three randomized, controlled trials of the use of N-9 contraceptives by commercial sex workers (CSWs) in Africa failed to demonstrate any protection against HIV infection (2--4); one trial showed an increased risk (3). N-9 contraceptives also failed to protect against infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in two randomized trials (5,6), one among African CSWs and one among U.S. women recruited from an STD clinic. Because most women in the African studies had frequent sexual activity, had high-level exposure to N-9 and probably were exposed to a population of men with a high prevalence of HIV/STDs, the implications of these studies for U.S. women are uncertain. To determine the extent of N-9 contraceptive use among U.S. women, CDC assessed data provided by U.S. family planning clinics for 1999. This report summarizes the results of that assessment, which indicate that some U.S. women are using N-9 contraceptives. Sexually active women should consider their individual HIV/STD infection risk when choosing a method of contraception. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections.

CDC collected information on types of N-9 contraceptives purchased and family planning program (FPP) guidelines for N-9 contraceptive use. The national FPP, authorized by Title X of the Public Health Service Act, serves approximately 4.5 million predominantly low-income women each year. Program data for 1999 were obtained from all 10 U.S. Department of Health and Human Services (HHS) regions on the number of female clients and the number of female clients who reported use of N-9 contraceptives or condoms as their primary method of contraception. CDC obtained limited purchase data for 1999 for specific N-9 contraceptives and program guidelines from eight state/territorial FPPs within six HHS regions. State health departments, family planning grantees and family planning councils were contacted to request assistance in collecting data on purchasing patterns of the 91 Title X grantees; of the 12 FPPs that responded, eight provided sufficient data for analysis.

In 1999, a total of 7%--18% of women attending Title X clinics reported using condoms as their primary method of contraception. Data on the percentage of condoms lubricated with N-9 were not available. A total of 1%--5% of all women attending Title X clinics reported using N-9 contraceptives (other than condoms) as their primary method of contraception ([Table 1](#)). Among the eight FPPs that provided purchase data, most (87%)

condoms were N-9--lubricated ([Table 2](#)). All eight FPPs purchased N-9 contraceptives (i.e., vaginal films and suppositories, jellies, creams and foams) to be used either alone or in combination with diaphragms or other contraceptive products. Four of the eight clinics had protocols or program guidance stating that N-9--containing foam should be dispensed routinely with condoms; two additional programs reported that despite the absence of a clinic protocol, the practice was common. Data for the other two programs were not available.

Reported by: *The Alan Guttmacher Institute, New York, New York. Office of Population Affairs, U.S. Dept of Health and Human Services, Bethesda, Maryland. A Duerr, MD, C Beck-Sague, MD, Div Reproductive Health, National Center Chronic Disease and Public Health Promotion; Div of HIV and AIDS Prevention, National Center HIV/AIDS, STDs and TB Prevention; B Carlton-Tohill, EIS Officer, CDC.*

Editorial Note:

The findings in this report indicate that in 1999, before the release of recent publications on N-9 and HIV/STDs ([4,6,7](#)), Title X family planning clinics in the U.S. purchased and distributed N-9 contraceptives. Among at least eight family planning clinics, most of the condoms purchased were N-9--lubricated; this is consistent with trends in condom purchases among the general public ([8](#)). The 2002 STD treatment guidelines state that condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV infection and other STDs ([7](#)). CDC recommends that previously purchased condoms lubricated with N-9 spermicide continue to be distributed provided the condoms have not passed their expiration date. The amount of N-9 on a spermicide-lubricated condom is small relative to the doses tested in the studies in Africa and the use of N-9--lubricated condoms is preferable to using no condom at all. In the future, purchase of condoms lubricated with N-9 is not recommended because of their increased cost, shorter shelf life, association with urinary tract infections in young women and lack of apparent benefit compared with other lubricated condoms ([7](#)).

Spermicidal gel is used in conjunction with diaphragms ([1](#)); only diaphragms combined with the use of spermicide are approved as contraceptives. The respective contributions of the physical barrier (diaphragm) and chemical barrier (spermicide) are unknown, but the combined use prevents approximately 460,000 pregnancies in the United States each year ([1](#)).

The findings in this report are subject to at least two limitations. First, data on specific products and patterns of contraceptive use were limited; CDC used a nonrepresentative sample of regions and states that voluntarily provided data and specific use patterns of the contraceptives could not be extrapolated from these data. Second, data correlating use of N-9 contraceptives with individual HIV risk were not available.

Prevention of both unintended pregnancy and HIV/STD infection among U.S. women is needed. In 1994, a total of 49% of all pregnancies were unintended ([9](#)). Furthermore, 26%

of women experience an unintended pregnancy during the first year of typical use of spermicide products (1). In 1999, a total of 10,780 AIDS cases, 537,003 chlamydia cases and 179,534 gonorrhea cases were reported among U.S. women. Contraceptive options should provide both effective fertility control and protection from HIV/STDs; however, the optimal choice is probably not the same for every woman.

N-9 alone is not an effective means to prevent infection with HIV or cervical gonorrhea and chlamydia (2,7). Sexually active women and their health-care providers should consider risk for infection with HIV and other STDs and risk for unintended pregnancy when considering contraceptive options. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections. In addition, women seeking a family planning method should be informed that latex condoms, when used consistently and correctly, are effective in preventing transmission of HIV and can reduce the risk for other STDs.

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Notice to Readers: CDC Statement on Study Results of Product Containing Nonoxynol-9

During the XIII International AIDS Conference held in Durban, South Africa, July 9--14, 2000, researchers from the Joint United Nations Program on AIDS (UNAIDS) presented results of a study of a product, COL-1492,* which contains nonoxynol-9 (N-9) (*I*). N-9 products are licensed for use in the United States as spermicides and are effective in preventing pregnancy, particularly when used with a diaphragm. The study examined the use of COL-1492 as a potential candidate microbicide, or topical compound to prevent the transmission of human immunodeficiency virus (HIV) and sexually transmitted diseases (STDs). The study found that N-9 did not protect against HIV infection and may have caused more transmission. The women who used N-9 gel became infected with HIV at approximately a 50% higher rate than women who used the placebo gel.

CDC has released a "Dear Colleague" letter that summarizes the findings and implications of the UNAIDS study. The letter is available on the World-Wide Web, <http://www.cdc.gov/hiv>; a hard copy is available from the National Prevention Information Network, telephone (800) 458-5231. Future consultations will be held to re-evaluate guidelines for HIV, STDs, and pregnancy prevention in populations at high risk for HIV infection. A detailed scientific report will be released on the Web when additional findings are available.

Reference

1. van Damme L. Advances in topical microbicides. Presented at the XIII International AIDS Conference, July 9--14, 2000, Durban, South Africa.

* Use of trade names and commercial sources is for identification only and does not constitute endorsement by CDC or the U.S. Department of Health and Human Services.

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Appendix D

Suggestions for Handling Problem Behavior



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Suggestions for Handling Problem Behavior

BEHAVIOR	POSSIBLE CAUSES	FACILITATOR RESPONSES
One participant argues frequently	<ul style="list-style-type: none"> • Likes to be the center of attention. • Wants to keep people from getting close. • Angry about something. • Upset about personal problems. • Needs to dominate. • Thinks arguing demonstrates intelligence. • Doesn't know another way to interact socially. 	<ul style="list-style-type: none"> • Keep the group calm. • Obtain Feeling Thermometer reading. • Use relaxation exercises to bring the tension level down if needed. • Find points in what the person is saying that have merit. • Engage the person in an assertiveness role play. • Have the person practice self-talk in a provocative situation. • Have the group brainstorm pros and cons regarding the points being made. • In a private moment ask what is bothering the person.
Several participants argue frequently	<ul style="list-style-type: none"> • Don't like each other. • May be members of opposing cliques. • Lack skills in social problem solving or assertiveness. 	<ul style="list-style-type: none"> • Emphasize points of agreement. • Point out objectives that cut across both positions. • Create role plays for others to perform on resolving the conflict. • Have members find positive qualities in the opponents. • Give out praise for positive behavior. • Emphasize that group members can be good and still present troublesome behaviors.
Participant won't talk	<ul style="list-style-type: none"> • Is frightened. • Feels insecure. • Is bored. • Is indifferent. • Feels superior. • Knows all the answers, or thinks he or she does. • Wants to be drawn out. • Is depressed. 	<ul style="list-style-type: none"> • Give praise for any small response. • Obtain Feeling Thermometer reading and discuss. • Ask for help in reading a script or role playing. • Assign work in pairs. • Encourage the group to give the person Thanks Tokens for participation. • If the person is depressed, provide a referral for individual counseling. • Say, "Let's hear from someone we haven't heard from today".
Participant is overly talkative	<ul style="list-style-type: none"> • Participant is eager to share and earn praise. • Participant needs to show off and receive attention. • Participant may know a great deal and want to show it. • Participant typically talks a great deal. • Participant may feel nervous or insecure. 	<ul style="list-style-type: none"> • Don't put participant down. • Ask thoughtful questions to make the person pause. • Interrupt with, "That's an interesting point. What do other people in the group think about it?" • Take the person aside and say that you need help in letting other group members have the experience of coming up with answers.
Participant is disruptive	<ul style="list-style-type: none"> • Causing trouble gets attention of Facilitator. • Angry about something and doesn't know how else to express it. • Trying to hide feelings of insecurity. • Looking for peer respect. • In emotional pain. 	<ul style="list-style-type: none"> • Ignore, redirect, and reward. • Give praise when the person is calm. • Invite to role play a part. • Divide participants into small groups; put the disruptive person with strong peers. • Stay physically close in order to reinforce appropriate behavior through Thanks Tokens. • Ask the client to take a five minute break. • Ask the client to leave and come back next time.

Suggestions for Handling Problem Behavior - *continued*

BEHAVIOR	POSSIBLE CAUSES	FACILITATOR RESPONSES
Participant complains frequently	<ul style="list-style-type: none"> • May have legitimate reason to complain. • Has a pet peeve. • Gripping is participant's personal style. • Has a great many dysfunctional thoughts. 	<ul style="list-style-type: none"> • See if appropriate changes can be made. • Point out what can be changed and what can't. • Use Feeling Thermometer and explore feelings behind the thoughts. • Involve the group in addressing the issues. • Create a role play where someone is unhappy and wants to bring about change, using "I" statements. • Discuss the complaints privately.
Participant rambles	<ul style="list-style-type: none"> • Is anxious. • Isn't clear about topic. • Wants to contribute but doesn't know how. • Has trouble concentrating. • Bothered by dysfunctional thoughts. • Is trying to impress but is unsure. 	<ul style="list-style-type: none"> • Orient to the topic. • Refocus the group. • Interrupt with a question about the topic at hand. • Ask the group to respond to the person's comments. • Give praise and Thanks Tokens for any comments that lead back to topic. • Say, "That's interesting, but I don't think I'm clear about how that relates to this". • Give the person a task to respond to and ask the person to think aloud, helping him or her stay focused. • Model staying on target.
Participant takes a stand and refuses to change	<ul style="list-style-type: none"> • Believes strongly in a particular point of view. • Connects position with self-esteem. • Is opinionated. • Hasn't understood other points of view. • Feels threatened. 	<ul style="list-style-type: none"> • Ask the person to argue against own viewpoint. • Have the group respond to the point of view. • Ask the person to repeat back the other positions that have been stated. • Get Feeling Thermometer readings and explore source of any discomfort. • Give Thanks Tokens for believing strongly and for expressing other positions.
Participant focuses on wrong topic	<ul style="list-style-type: none"> • Doesn't understand the direction of the session and the group. • Has a personal agenda. • Needs to feel assertive. • Doesn't want to deal with the topic at hand. 	<ul style="list-style-type: none"> • Take the blame. Say, "Something I said must have gotten you off the topic. We're talking about _____". • Try to find out if the topic the person is on has a personal significance. • Ask the group if the person's topic is one that needs to get dealt with. • Ask the person to think about the correct topic and then give a Feeling Thermometer reading; explore where any discomfort is coming from.
Participant constantly seeks the Facilitator's point of view	<ul style="list-style-type: none"> • Wants attention, praise. • Looking for advice. • Trying to copy the leader's behavior. • Doesn't understand what position is the best one to take. • Wants to challenge the Facilitator. 	<ul style="list-style-type: none"> • Give Thanks Tokens for participating and paying attention. • Throw questions back to the group. • Give direct answers if appropriate. • Don't take away the person's opportunity to solve his or her own problem. • Ask for situations that demonstrate the question and role play them.
Participant cannot read well	<ul style="list-style-type: none"> • Never had opportunity to learn. • Is dyslexic. • Needs glasses. • Has eye problem. 	<ul style="list-style-type: none"> • Have another group member assist with prompting. • Have another group member be the person's shadow and take over only the reading part of the exercises. • Give Thanks Tokens for trying. • Arrange for outside assistance on the basic problem.

BEHAVIOR	POSSIBLE CAUSES	FACILITATOR RESPONSES
Participant makes incorrect statements	<ul style="list-style-type: none"> Doesn't know the facts. Believes myths about the topic. Goes along with peer group distortions. 	<ul style="list-style-type: none"> Ask the person what the consequences of the statement would be. Ask the group to react to the statement. Accept that the person does believe it with, "I can see how you feel," or, "That's one way of looking at it". Say, "I see your point, but how does it fit with _____?" Have the group try to figure out how such a belief got started. Make sure the person doesn't end up feeling stupid or embarrassed.
Participant speaks in an inarticulate way	<ul style="list-style-type: none"> Feels awkward speaking in a group. Has ideas but is unsure how to express them appropriately. 	<ul style="list-style-type: none"> Don't say, "What you mean is this". Ask, "Do you mean," and then rephrase in more appropriate language what you think the participant may have been trying to say. Have the person write out what he or she wants to say and then coach him or her. Pair the person with someone else who will model the desired language when they work together on a task. Praise participant language that comes close to expressing the ideas appropriately. Have the person make very small presentations at first.
Participant is consistently late	<ul style="list-style-type: none"> Has outside responsibilities that interfere (child care, job, school). Is hostile to group. Angry at HIV status. 	<ul style="list-style-type: none"> Speak to participant and discover why; problem-solve a solution; set boundaries. Serve food ½ hour before start time, then remove it. Ask group for recommendations.
Participant comes to session drunk or high	<ul style="list-style-type: none"> One-time slip up. Dependency problem. 	<ul style="list-style-type: none"> Refer to ground rules and ask participant to leave until sober. Process with group. Speak to participant outside of group.



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Appendix E

Sample Outcome Monitoring Form and TLC Pre- and Post-Intervention Survey



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Sample Outcome Monitoring Form and TLC Pre- and Post-Intervention Survey

Each agency's funding source will have different requirements for process monitoring, process evaluation, and outcome monitoring. This Appendix includes forms that are supplied as suggestions. Each can be modified to fit your agency's requirements, target population, resources, and needs. Included are a Sample Outcome Monitoring Form, and a Pre- and Post-Intervention Survey. Agencies should consult their funder for evaluation requirements and standards.

Sample Outcome Monitoring Form

Condom Use and Sexual Risk Behaviors

Initial Outcome Monitoring Interview

Follow-up Outcome Monitoring Interview

GENERAL SEXUAL ACTIVITY

1. During the past 12 months, have you had sex with anyone?

- [1] Yes
- [2] No (Skip to Q 10)
- [9] Refused

2. During the past 12 months, have you had sex with only males, only females, or both?

- [1] Only males
- [2] Only females
- [3] Both males and females
- [9] Refused

1. Since your last interview, have you had sex with anyone?

- [1] Yes
- [2] No (Skip to Q 15)
- [9] Refused

2. Since your last interview, have you had sex with only males, only females, or both?

- [1] Only males
- [2] Only females
- [3] Both males and females
- [9] Refused

SEX AND CONDOM USE WITH MAIN PARTNERS

3. During the past 12 months, have you had a main sex partner?

- [1] Yes
- [2] No (Skip to Q 7)
- [9] Refused

4. Is your main sex partner male or female?

- [1] Male
- [2] Female
- [9] Refused

5. The last time you had sex with your main partner, what type of sex did you have? (Check all that apply)

- [1] Oral
- [2] Vaginal
- [3] Anal
- [4] Other (Specify _____)
- [9] Refused

6. The last time you had sex with your main partner, did you or your partner use a condom?

- [1] Yes
- [2] No
- [8] Cannot Remember/Don't Know
- [9] Refused

3. Since your last interview, have you had a main sex partner?

- [1] Yes
- [2] No (Skip to Q 7)
- [9] Refused

4. Is your main sex partner male or female?

- [1] Male
- [2] Female
- [9] Refused

5. The last time you had sex with your main partner, what type of sex did you have? (Check all that apply)

- [1] Oral
- [2] Vaginal
- [3] Anal
- [4] Other (Specify _____)
- [9] Refused

6. The last time you had sex with your main partner, did you or your partner use a condom?

- [1] Yes
- [2] No
- [8] Cannot Remember/Don't Know
- [9] Refused

Condom Use and Sexual Risk Behaviors

Initial Outcome Monitoring Interview

Follow-up Outcome Monitoring Interview

SEX AND CONDOM USE WITH NON-MAIN PARTNERS

7. During the past 12 months, have you had sex with someone who is not your main partner or whom you did not consider your main partner at that time?
- [1] Yes
[2] No (Skip to Q 10)
[9] Refused
8. The last time you had sex with someone who is not your main partner, what type of sex did you have? (Check all that apply)
- [1] Oral
[2] Vaginal
[3] Anal
[4] Other (Specify _____)
[9] Refused
9. The last time you had sex with someone who is not your main partner, did you or your partner use a condom?
- [1] Yes
[2] No
[8] Cannot Remember/Don't Know
[9] Refused

7. Since your last interview, have you had sex with someone who is not your main partner or whom you did not consider your main partner at that time?
- [1] Yes
[2] No (Skip to Q 10)
[9] Refused
8. The last time you had sex with someone who is not your main partner, what type of sex did you have? (Check all that apply)
- [1] Oral
[2] Vaginal
[3] Anal
[4] Other (Specify _____)
[9] Refused
9. The last time you had sex with someone who is not your main partner, did you or your partner use a condom?
- [1] Yes
[2] No
[8] Cannot Remember/Don't Know
[9] Refused

SEX PARTNER RISKS

10. Have you ever had sex in exchange for money, drugs, or shelter?
- [1] Yes
[2] No
[8] Cannot Remember/Don't Know
[9] Refused
11. Have you ever had sex with someone whom you knew or suspected of having HIV/AIDS?
- [1] Yes
[2] No
[8] Don't Know
[9] Refused
12. Have you ever had sex with someone whom you knew or suspected of being an injecting drug user?
- [1] Yes
[2] No
[8] Don't Know
[9] Refused

10. Since your last interview, have you had sex in exchange for money, drugs, or shelter?
- [1] Yes
[2] No
[8] Cannot Remember/Don't Know
[9] Refused
11. Since your last interview, have you had sex with someone whom you knew or suspected of having HIV/AIDS?
- [1] Yes
[2] No
[8] Don't Know
[9] Refused
12. Since your last interview, have you ever had sex with someone whom you knew or suspected of being an injecting drug user?
- [1] Yes
[2] No
[8] Don't Know
[9] Refused

Sample Outcome Monitoring Form - *continued*

Condom Use and Sexual Risk Behaviors

Initial Outcome Monitoring Interview

Follow-up Outcome Monitoring Interview

SEX PARTNER RISKS

13. The last time you had sex, did you use injected drugs or alcohol?

[1] Yes

[2] No

[8] Cannot Remember

[9] Refused

14. The last time you had sex, did you use any non-injected drugs or alcohol?

[1] Yes

[2] No

[8] Cannot Remember

[9] Refused

13. The last time you had sex, did you use injected drugs or alcohol?

[1] Yes

[2] No

[8] Cannot Remember

[9] Refused

14. The last time you had sex, did you use any non-injected drugs or alcohol?

[1] Yes

[2] No

[8] Cannot Remember

[9] Refused

STD/HIV STATUS

15. During the past 12 months, has anyone told you that you had a sexually transmitted disease, or STD, for example, herpes, gonorrhea, chlamydia, genital warts?

[1] Yes

[2] No

[8] Cannot Remember/Don't Know

[9] Refused

16. Have you ever been told by a doctor or other health professional that you were infected with HIV or that you have AIDS?

[1] Yes

[2] No

[8] Cannot Remember/Don't Know

[9] Refused

15. Since your last interview, has anyone told you that you had a sexually transmitted disease, or STD, for example, herpes, gonorrhea, chlamydia, genital warts?

[1] Yes

[2] No

[8] Cannot Remember/Don't Know

[9] Refused

16. Since your last interview, have you ever been told by a doctor or other health professional that you were infected with HIV or that you have AIDS?

[1] Yes

[2] No

[8] Cannot Remember/Don't Know

[9] Refused

Injection Drug Use and Other Drug-Related Risks

Initial outcome monitoring interview	Follow-up outcome monitoring interview
<p>1. Have you ever, even once, used a needle to inject a drug that was not prescribed for you?</p> <p>[1] Yes</p> <p>[2] No (Skip to Q 11)</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused (Skip to Q 11)</p>	<p>1/2. Since your last interview, have you used a needle to inject a drug that was not prescribed for you?</p> <p>[1] Yes</p> <p>[2] No (Skip to Q 11)</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused (Skip to Q 11)</p>
<p>2. In the past 12 months, have you ever used a needle to inject a drug that was not prescribed for you?</p> <p>[1] Yes</p> <p>[2] No (Skip to Q 11)</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused (Skip to Q 11)</p>	
<p>3. The last time you used a needle for injecting drugs, where did you get the needle from?</p> <p>[1] Pharmacy</p> <p>[2] Needle exchange</p> <p>[3] Street</p> <p>[4] Shooting gallery</p> <p>[5] Friend</p> <p>[6] Dealer</p> <p>[7] Other (Specify _____)</p>	<p>3. The last time you used a needle for injecting drugs, where did you get the needle from?</p> <p>[1] Pharmacy</p> <p>[2] Needle exchange</p> <p>[3] Street</p> <p>[4] Shooting gallery</p> <p>[5] Friend</p> <p>[6] Dealer</p> <p>[7] Other (Specify _____)</p>
<p>4. The last time you used a needle for injecting drugs, was it a new and unused needle? (A needle in an unopened package or with an intact seal)</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>	<p>4. The last time you used a needle for injecting drugs, was it a new and unused needle? (A needle in an unopened package or with an intact seal)</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>
<p>5. The last time you used a needle to inject drugs, what drug did you inject?</p> <p>[1] Heroin</p> <p>[2] Cocaine</p> <p>[8] Speedball (heroin and cocaine together)</p> <p>[9] Methamphetamine</p>	<p>5. The last time you used a needle to inject drugs, what drug did you inject?</p> <p>[1] Heroin</p> <p>[2] Cocaine</p> <p>[8] Speedball (heroin and cocaine together)</p> <p>[9] Methamphetamine</p>
<p>6. The last time you used a needle to inject drugs, did you know or suspect someone else had used it before you?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>	<p>6. The last time you used a needle to inject drugs, did you know or suspect someone else had used it before you?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>

Sample Outcome Monitoring Form - *continued*

Injection Drug Use and Other Drug-Related Risks	
Initial outcome monitoring interview	Follow-up outcome monitoring interview
<p>7. Have you ever used a needle that you knew or suspected someone else had used before you?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot Remember/Don't Know</p> <p>[9] Refused</p>	<p>7. Since your last interview, have you ever used a needle that you knew or suspected someone else had used before you?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot Remember/Don't Know</p> <p>[9] Refused</p>
<p>8. Did you use bleach (or other solutions) to clean the needle before you used it?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>	<p>8. Did you use bleach (or other solutions) to clean the needle before you used it?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>
<p>9. The last time you used a needle for injecting drugs, did someone else use the needle after you?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>	<p>9. The last time you used a needle for injecting drugs, did someone else use the needle after you?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>
<p>10. The last time you used a needle for injecting drugs, did you have sex with someone while you were high?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>	<p>10. The last time you used a needle for injecting drugs, did you have sex with someone while you were high?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>
<p>11. In the past 12 months, have you smoked, sniffed, or taken drugs that you did not inject?</p> <p>[1] Yes</p> <p>[2] No (Stop)</p> <p>[8] Cannot remember/ Don't Know (Stop)</p> <p>[9] Refused (Stop)</p>	<p>11. Since your last interview, have you smoked, sniffed, or taken drugs that you did not inject?</p> <p>[1] Yes</p> <p>[2] No (Stop)</p> <p>[8] Cannot remember/ Don't Know (Stop)</p> <p>[9] Refused (Stop)</p>

Injection Drug Use and Other Drug-Related Risks

Initial outcome monitoring interview	Follow-up outcome monitoring interview
<p>12. The last time you used drugs that you did not inject, what did you use? (Check all that apply)</p> <p>[1] Crack</p> <p>[2] Cocaine</p> <p>[3] Heroin</p> <p>[4] Methamphetamine/Speed/Crystal</p> <p>[5] Downers/Tranquilizers (Valium, etc.)</p> <p>[6] Ecstasy</p> <p>[7] Barbiturates</p> <p>[8] PCP (angel dust)</p> <p>[9] Nitrites</p> <p>[10] LSD</p> <p>[11] Inhalants</p> <p>[12] Alcohol</p> <p>[13] Other (Specify _____)</p> <p>[99] Cannot remember/Don't Know</p> <p>13. How did you use the drug? (Check all that apply)</p> <p>[1] Snort</p> <p>[2] Sniff</p> <p>[3] Inhale</p> <p>[4] Smoke</p> <p>14. The last time you used non-injected drugs, did you have sex with someone while you were high?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>	<p>12. The last time you used drugs that you did not inject, what did you use? (Check all that apply)</p> <p>[1] Crack</p> <p>[2] Cocaine</p> <p>[3] Heroin</p> <p>[4] Methamphetamine/Speed/Crystal</p> <p>[5] Downers/Tranquilizers (Valium, etc.)</p> <p>[6] Ecstasy</p> <p>[7] Barbiturates</p> <p>[8] PCP (angel dust)</p> <p>[9] Nitrites</p> <p>[10] LSD</p> <p>[11] Inhalants</p> <p>[12] Alcohol</p> <p>[13] Other (Specify _____)</p> <p>[99] Cannot remember/Don't Know</p> <p>13. How did you use the drug? (Check all that apply)</p> <p>[1] Snort</p> <p>[2] Sniff</p> <p>[3] Inhale</p> <p>[4] Smoke</p> <p>14. The last time you used non-injected drugs, did you have sex with someone while you were high?</p> <p>[1] Yes</p> <p>[2] No</p> <p>[8] Cannot remember/ Don't Know</p> <p>[9] Refused</p>

TLC Pre- and Post-Intervention Survey

Please answer the following questions to help <Name of Implementing Agency> and its HIV prevention programs gather information to help with their HIV prevention efforts. Your answers are anonymous. Thanks for your help.

1. How old are you? _____

Please circle the number next to the response which best reflects your answer.

2. What is your sex? Female..... 1 Male..... 2 Transgender 3

3. What is your ethnicity?

Asian/Pacific Islander 1 Native American.....4
African American 2 Caucasian.....5
Latino/a..... 3 Other_____ 6 (Please Specify)

4. How do you identify yourself? (Circle one)

Homosexual/Gay.....1 Bisexual2 Heterosexual.....3

5. What is the zip code where you live?_____

6. Do you live in <local city>? Yes. . . . 1 No. . . . 2

7. Do you work in <local city>? Yes. . . . 1 No. . . . 2

To help prevent the spread of HIV, the <Name of Implementing Agency> needs to know about risk behaviors of young people. Some of these questions are personal. You may choose not to answer any questions. We appreciate your cooperation in answering the following questions. Please check the box next to the response which best reflects your answer.

8. In the last 3 months, have you had sex?

- Yes
- No (Skip to Question #12)
- Refused to Answer (Ref)

9. If yes, how many sex partners did you have?

Number of men _____
Number of women _____
Don't Know (DK) _____
Refused to Answer (Ref) _____

10. In the last 3 months, how often did you or your partner(s) use condoms for anal sex?

- Always
- Most of the time
- Sometimes
- Never
- Don't Know (DK)
- Refused to Answer (Ref)
- Not Applicable (NA)

11. In the past 3 months, have you had unprotected sex with someone whom you knew had HIV/AIDS?

- Yes
- No
- Don't Know (DK)
- Refused to Answer (Ref)

12. In the past 3 months, did you use? (Check all that apply)

- Crystal
- Ecstasy
- Cocaine
- Crack
- Heroin
- Amphetamine/Speed (pills)
- Downers/Tranquilizers (Valium, etc.)
- Nitrites
- LSD
- Inhalants
- Alcohol
- Other: (Specify): _____

13. In the last 3 months, did you have sex with someone while you were high on drugs and/or alcohol?

- Yes
- No
- Don't Know (Dk)
- Refused to Answer (Ref)

Please answer the following true or false statements regarding HIV safer sex behaviors and HIV testing. Circle T if you think the statement is True and F if you think the statement is False.

17. It takes a minimum of three weeks after exposure before the HIV antibody will show up on an HIV test.

- T
- F

18. Using heavy drugs or alcohol before sex can impair your judgment about condom use.

- T
- F

19. You can prevent the transmission of HIV during anal sex by withdrawing before ejaculation.

- T
- F

20. You can prevent the transmission of HIV during anal sex by using a latex condom and water-based lubricant.

- T
- F

Thank you for completing this survey.



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Appendix F

Ewart Article on Social Action Theory



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Social Action Theory for a Public Health Psychology

Craig K. Ewart

Department of Health Policy and Management, Johns Hopkins University

Many illnesses can be prevented or limited by altering personal behavior, and public health planners have turned to psychology for guidance in fostering self-protective activity. A social theory of personal action provides an integrative framework for applying psychology to public health, disclosing gaps in our current understanding of self-regulation, and generating guidelines for improving health promotion at the population level. A social action view emphasizes social interdependence and interaction in personal control of health-endangering behavior and proposes mechanisms by which environmental structures influence cognitive action schemas, self-goals, and problem-solving activities critical to sustained behavioral change. Social action theory clarifies relationships between social and personal empowerment and helps explain stages of self-change.

Every year millions of people suffer and die of illnesses that could be curbed or eliminated by altering patterns of personal behavior. Modifiable habits and customs contribute to malnutrition, communicable diseases, and chronic illnesses, and thereby augment a staggering toll of needless deaths (Elder, 1987). To lower this toll, public health planners have turned to psychology—and especially to its models of self-regulation—for guidance in fostering self-protective action among those at risk. Yet psychological theories and models often seem of limited value when applied to public health problems, and some public health theorists have questioned their usefulness in the global struggle against disease (Jeffery, 1989; Leventhal, Cleary, Safer, & Gutman, 1980). I argue that psychology *does* have a role to play, but that this role is constrained by inattention to pathways by which social environmental phenomena affect cognitive and biologic regulatory processes. I propose a theory of personal action designed to foster social-contextual analysis of personal change. This analysis poses important questions for self-regulation theory and discloses new opportunities for psychology to contribute to human health and well-being.

Public Health and Psychology

The term *public health* embraces a diverse array of problem-solving and health-protective activities inspired by the practice of viewing illnesses in a social context. By relating the afflictions of individuals to the groups to which they belong or to the environments in which they work and live, the public health outlook differs from that of clinical medicine, which treats diseases as attributes of isolated sufferers. This social-contextual approach has

advanced disease control and enhanced quality of life in ways that would not have been possible in a clinical model. Early attempts to determine who became sick, and where and when, for example, led to significant reductions in the prevalence of infectious diseases long before the biological mechanisms of these illnesses could be explained or modified. A population perspective can reveal a previously unrecognized environmental hazard or a widespread health-endangering personal behavior that when altered even slightly may reduce the burden of human suffering and lower the cost of medical care. This perspective has led to public health's long-standing emphasis on disease prevention and on viewing the entire community—rather than the individual—as the patient.

Public health's interest in individuals and in processes of personal change has increased, however, with mounting evidence linking major health threats to modifiable human behaviors (Sexton, 1979; Surgeon General, 1979). Public health is an empirically driven, problem-focused enterprise that looks to various disciplines for needed theoretical and technical resources. Yet those who would apply behavior change methods of psychology to populations quickly discover that these efforts can go awry (Jeffery, 1989). Interventions directed at individuals can prove more expensive than the "passive" environmental prevention strategies long championed in the public health movement and may unintentionally "blame the victim" by implying that people are personally responsible for illnesses caused by unhealthy physical and social environments (Runyan, DeVellis, DeVellis, & Hochbaum, 1982; Williams, 1982). Moreover, the dominant diagnostic model in public health envisions an interaction between a host (e.g., disease victim), an agent (e.g., health-damaging organism or substance), and the environment. Psychological theories focus on the host. They explain important phenomena of individual learning, memory, choice, and performance. Yet public health planners often have difficulty applying these theories to the practical tasks of designing protective legislation, educating the public, and fashioning healthier occupational work or living environments (Faden, 1987). These tasks require a multi-leveled conception that views host processes as subcomponents of larger social and environmental systems.

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Self-Regulation

By the mid 1970s, interventions based on social learning principles were seen to offer the most effective, widely applicable method for changing behaviors that contributed to leading causes of preventable deaths (e.g., Bandura, 1969; Kanfer, 1977). With its emphasis on cognitive mediation of learning through modeling and vicarious reinforcement, social learning theory stimulated the creation of interventions to prevent heart disease and cancer by altering habits related to eating (Stunkard & Penick, 1979), smoking (Leventhal & Cleary, 1980), exercise (Martin et al., 1984), and substance use (Marlatt & Gordon, 1985). These developments provided both a theoretical and a practical foundation for communitywide interventions such as the Stanford Five-Community Study (Farquhar et al., 1985) and the Minnesota Heart Health Program (Blackburn et al., 1984). During the 1980s, social learning theorists expanded their purview to include a variety of cognitive phenomena subsumed under the rubric "social-cognitive theory" (Bandura, 1986), and control and systems concepts were incorporated into models of self-regulation (Bandura, 1989; Carver & Scheier, 1981; Hyland, 1988; Schwartz, 1983). Goals, feedback functions, and attendant systems constructs helped delineate processes by which people overcame destructive behavior patterns and strengthened self-protective capabilities (Weinstein, 1988).

Social Action Theory

Although these developments expand a theory of personal change, they do not meet public health's need for a contextual theory of individual action that incorporates modifiable social and personal mechanisms of self-control within an environmental model. Those who would encourage self-regulation on a wide scale require a framework for solving the problems that have hindered attempts to implement self-change as a public health strategy (Leventhal, Zimmerman, & Gutman, 1984), including the challenge of defining appropriate self-regulatory goals, the problem of identifying causal mechanisms that can be activated to facilitate these goals, and the task of uncovering social-contextual influences that constrain or enhance self-regulatory mechanisms and thus provide targets for political, economic, or organizational change.

This article responds to this need by proposing a conceptual model with three dimensions representing self-regulation as a desired *action state*, an ensemble of interrelated *change mechanisms*, and a subcomponent of larger social environmental systems that *contextually* determine how personal change mechanisms operate. The proposed framework seeks to identify self-regulatory phenomena of public health importance, stimulate a desire to understand them, and set forth basic assumptions to guide the development of new theories, models, and exemplars (Kuhn, 1977; Rappaport, 1987). In this view, interventions to encourage self-regulation belong to the public health tradition of inoculation. As immunization strengthens the self-regulatory capabilities of the immune

system, so behavioral interventions strengthen self-regulatory systems that foster capacity for self-protective action (Ewart, in press). These self-regulatory systems can be viewed as interconnected cybernetic control loops operating at physiologic, cognitive, and social levels (Seeman, 1989).¹

Applying the framework to an analysis of population interventions discloses gaps in our current understanding of self-regulation and suggests how public health strategies targeting individuals might be improved. To highlight these problems and possibilities, I apply here the tripartite model to self-regulation of coronary and cancer risk behaviors involving diet, physical activity, and tobacco or alcohol use, as these have generated the largest health literature on self-regulation. The model's three dimensions (Figure 1), respectively, emphasize the role of social context in maintaining health routines or habits (action state dimension), provide a causal framework linking self-change processes to interpersonal environments (process dimension), and specify macrosocial and environmental influences that empower or constrain personal change (contextual dimension).²

Self-Regulation as an Action State

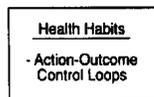
The first challenge in public health intervention is to define appropriate self-regulatory goals. In most cases, prevention entails creating self-protective habits in the form of highly routinized and "automatic" action sequences that lower personal risk. Health habits are easily represented by a simple action-outcome feedback loop, in which self-regulation is a condition of self-sustaining, dynamic equilibrium between self-protective activities and their experienced biologic, emotional, and social consequences. Habitual eating, exercise, smoking, or drinking activities tend to follow predictable scripts, in which successive events in an action sequence reinforce preceding acts and guide subsequent action components (Kazdin, 1984; Schank & Abelson, 1977). These scripts tend to be highly integrated, in that one can perform them without consciously attending to component actions that compose the larger sequence (Abelson, 1981). Moreover, they often co-occur with other habitual acts, as when eating, smoking, or drinking are embedded in social or recreational events. This makes unwanted habits hard to change; conversely, the assimilation of desired habits into other rou-

¹ "Behavioral inoculation" can be effected via legal or environmental changes that encourage people to take self-protective action against a health threat. Laws requiring seat-belt use and buzzers reminding passengers to attach their belts represent inoculation approaches to preventing automobile injuries, whereas laws mandating air bags in vehicles—by reducing the need for personal action—represent public health's "sanitary" tradition of removing health threats from human environments. Research on self-regulation thus may aid legal and environmental intervention, as well as public education.

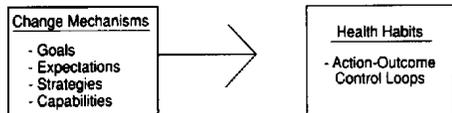
² The model also applies to behaviors contributing to malnutrition and to communicable diseases that, although less studied by psychologists, account for a far greater portion of the world's preventable deaths. For applications to third-world health problems and settings, see Elder (1987), and Elder, Schmid, Hovell, Molgaard, and Graeff, (1989).

Figure 1
Social-Contextual Model of Self-Regulation

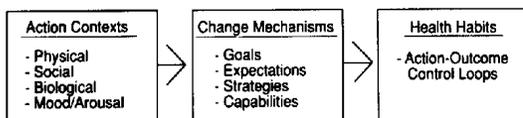
1. SELF-REGULATORY GOALS:



2. SELF-REGULATORY PROCESSES:



3. SOCIAL ACTION MODEL:



Note. 1. The goal of self-regulation is to create action–outcome control loops that sustain health-protective routines; 2. the process of self-regulation entails activating social–cognitive mechanisms to generate desired control loops; 3. social and biological contexts of self-regulation facilitate or constrain these mechanisms and thus determine long-term success in habit modification.

tines renders protective diet, exercise, or similar regimens easier to sustain (Ewart, in press).

In this feedback model, actions are guided by their consequences in a negative control loop; variations in monitored outcomes (immediate and delayed) evoke compensating behavioral adjustments. The result is a steady but continuously oscillating action state, in which the frequency of the diet, exercise, or other behavior fluctuates around some stable set point (D. H. Ford, 1987). The control loop implies that the starting place in developing public health interventions is with an analysis of the relationships between health-endangering action sequences and their experienced effects. This analysis can disclose the point at which problematic action scripts are most vulnerable to prevention, and suggest effective procedures for constructing new scripts to protect health (Ewart, in press). The action state model thus helps the intervention planner identify critical action components and specify desired replacement sequences and outcomes.

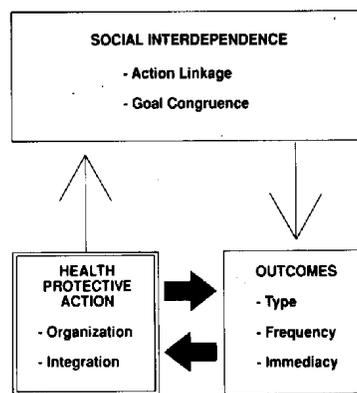
The functional feedback loop described here represents a dominant view in current models of self-regulation and, in a broader sense, exemplifies an evolutionary social behaviorism explicitly or tacitly assumed in the post-Darwinian functionalism of James, Freud, and Piaget, as well as in contemporary operant, social–cognitive, and psychoanalytic theories. The fact of its perpetual re-emergence in diverse forms over the past century suggests that this feedback mechanism ranks as one of the more significant discoveries of modern experimental and clin-

ical psychology (Woodward, 1982). Yet attempts to modify health habits in community-based prevention disclose that the intrapersonal control loops emphasized in psychological theories are connected to interpersonal control systems: Personal action scripts are socially intertwined with scripts of family members, friends, or others in ways that pose significant obstacles to long-term change (M. H. Becker & Green, 1975; Sallis, Grossman, Pinski, Patterson, & Nader, 1987). Public health applications reveal a need to expand individually focused action state conceptions by including interdependence with others as a determinant of sustained behavior change.

Social Interdependence

Figure 2 incorporates social interdependence into the action state model. A close social relationship is one in which important action scripts of the people involved are interlinked; each individual in the relationship has the ability to facilitate or impede the other's sequences and thus affect their ability to attain valued goals related to love, work, self-care, or other desired ends (Clark & Reis, 1988). These interlinked scripts frequently serve multiple goals. Preparing and sharing a meal, for example, allows family members to satisfy hunger, give and receive emotional support, amuse themselves, and plan the next day's activities (Bersheid, 1983). Social closeness can be defined in terms of the number of interlinked scripts and by the number of goals these linked sequences serve. As closeness increases, so does the probability that one person's attempt to alter a simple routine will disrupt valued routines and goals of intimate others, causing frustration and anger (Manne & Zautra, 1989; Ruchman & Wolchik, 1988). Changes that disrupt action sequences at a point close to

Figure 2
Action State Model Representing Self-Regulation as a Negative Control Loop Maintaining Habitual Action Sequences or Routines



Note. The model incorporates social interdependence (script linkage) into the conventional action–outcome feedback model.

the goal are more likely to provoke anger than are interruptions that occur farther from the goal (Mandler, 1975). A partner's negative reactions to interrupted routines can undermine commitment to new patterns of health behavior.

Note that in this model the degree of disruption, and hence of support from a helper, is predicted by the degree to which the helper's valued action scripts are interdependent with the action scripts of the person needing support (i.e., the degree of action linkage). This explains why measures of relationship satisfaction often fail to predict family members' responses to a member's change of diet, exercise, or other routines; behavioral support is a function of action linkage, whereas relationship satisfaction reflects the degree to which one's goals for the relationship are being met (Ewart, in press). Families characterized by high levels of cohesion and satisfaction (Olson, Sprenkle, & Russell, 1979) may prove surprisingly unsupportive when important interlinked routines are repeatedly disrupted (Coyne, Wortman, & Lehman, 1988); and family environments characterized by lower levels of cohesion or satisfaction may be conducive to behavior change if action linkage also is low.

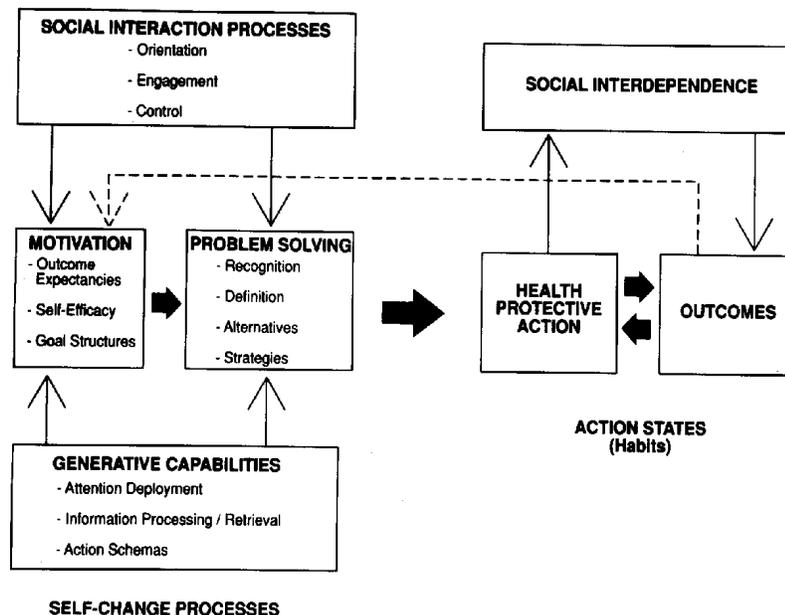
Self-regulation theorists have devoted scant attention to the counterintuitive notion that relationship closeness may be a risk factor for nonadherence, and few have considered that daily routines are as likely to disrupt health-

promoting action scripts as are health beliefs or attributions (Lichtman et al., 1984). Research examining the effect of script interdependence on health habit change has the potential to tie self-regulation theory to social contexts and to suggest methods for identifying and uncoupling potentially problematic action linkages (Bersheid, Snyder, & Omoto, 1989).

Processes of Self-Change

Behavioral interventions in populations require an action model that offers explicit procedural guidelines for encouraging personal self-regulation (Leventhal, Zimmerman, & Gutman, 1984). The action state model effectively describes habitual activities in which people react to feedback discrepancies occasioned by disrupted routines but does not fully represent processes involved in creating new action scripts or modifying ones that prove ineffective. The latter processes include "feed-forward" mechanisms by which people create new goals, alter self-standards, fashion behavioral strategies, and select new environments (cf. D. H. Ford, 1987, pp. 67-69). Social-cognitive research has identified a number of mechanisms that enable people to make transitions from old action states to new ones, and thus to change. It is useful to view these transition processes as interacting components within a general causal model, as in Figure 3. Figure 3

Figure 3
Process (Self-Change) Model Representing Self-Regulation as a Coordinated Ensemble of Interacting Cognitive Processes and Capabilities



Note. The model incorporates action capabilities of microsocial relationship systems (social interaction processes) into a general causal model of personal change.

introduces a process dimension to indicate that action states arise from strategies people use when trying to regulate their behavior, and that the creation of strategies is prompted by motivational appraisal processes. The ability to make appraisals and translate them into strategies is a function of health-relevant procedural and factual knowledge (generative capabilities), as well as the interpersonal skills possessed by oneself and by others with whom one's action scripts are interlinked (social interaction component). Note that self-change processes (Figure 3) are connected with action states via the broken line shown in the figure: Disturbance of an action state due to internal changes (e.g., fatigue or illness) or external causes (e.g., disrupted interdependence) may stimulate reappraisal, renewed problem solving, and strategy implementation, even as changes in appraisals, by suggesting new goals and strategies, may alter existing action states.

In addition to providing targets for intervention, process mechanisms suggest testable pathways through which environments can affect health behavior and provide new ways for public health epidemiologists and planners to envisage and to investigate person-environment interactions. I will return to this important point later when discussing contextual influences.

Problem Solving

Models of health behavior usually ascribe changes in health habits to changes in health knowledge, beliefs, attitudes, or contingencies of reinforcement (Janz & Becker, 1984; Leventhal et al., 1984). It is becoming evident, however, that problem-solving activities mediate the impact of these motivators; persuasive inducements affect behavior only to the degree that they prompt people to create appropriate self-change strategies. Strategies function as action guides for specific situations and range from simple *if-then* rules used without active awareness (Linville & Clark, 1989) to carefully constructed constellations of thoughts, feelings, and actions that help an actor regulate arousal, exert control over outcomes, make choices, and persist in the face of difficult obstacles (Dweck & Leggett, 1988; Kihlstrom, 1987; Langer, 1989).

Research conducted in the past decade suggests that the ability to generate effective strategies for handling day-to-day problems is related to social and emotional adjustment, and that adjustment can be enhanced by problem-solving training (D'Zurilla, 1986; Nezu, 1986; Nezu & Perri, 1989). Moreover, it appears that problem-solving activities constitute the fulcrum of the habit-change process. Adherence to dietary regimens is correlated with problem-solving skill in adults (Fehrenbach & Peterson, 1989; Glasgow, Toobert, Riddle, Donnelly, & Calder, 1989) and in adolescents (Hanna, Ewart, & Kwitrovich, 1990). Including problem-solving training in behavioral weight-loss interventions has been shown to effect greater weight loss than has comparable behavioral intervention without problem-solving training (Black & Scherba, 1983; Graves, Myers, & Clark, 1988). These findings suggest that, rather than focus only on target behaviors, public health interventions should encourage and enable people

to identify potential obstacles to self-change and generate appropriate strategies to overcome them.

Motivational Processes

People are neither impelled by attitudes nor mindlessly pulled by reinforcers. Instead, they actively motivate themselves by envisaging possible outcomes, evaluating their capabilities, and generating goals that guide and energize problem solving.

Outcome expectancies. Decisions to adopt health-protective behaviors are influenced by expectations that a recommended action will protect or enhance valued resources or outcomes (Bandura, 1986; Janz & Becker, 1984; Rogers, 1983). Anticipated outcomes include the health-promoting activity's intrinsic effects (e.g., the pleasant physical sensations it produces), as well as its more extrinsic material and social consequences (e.g., enhanced personal appearance, social approval, reduced risk). People contemplating a difficult action such as quitting smoking carefully weigh the pros and cons of acting; the relative importance they attribute to desired and undesired consequences of trying to quit predicts the probability of their acting, as well as the likelihood of their maintaining prolonged abstinence (Velicer, DiClemente, Prochaska, & Brandenburg, 1985). Leventhal and his associates (Baumann & Leventhal, 1985; Leventhal, Meyer, & Nerenz, 1980) have underscored the role of cognitive appraisals by demonstrating that many health choices are shaped by erroneous expectancies derived from idiosyncratic and incorrect "theories of illness." Public health interventions can alter outcome expectancies by drawing attention to naturally occurring outcomes (e.g., emphasize immediately experienced benefits of exercise or diet change), as well as by introducing contrived incentives (e.g., lottery prizes). In the case of behaviors that are comparatively uncomplicated or easy to perform (e.g., switching to a higher fiber cereal), significant widespread change often can be effected by providing information about action-consequence relationships and by introducing simple prompts into situations in which the self-protective action should be performed (e.g., the grocery store shelf; Geller, Winett, & Everett, 1982).

Although research in health belief and reasoned action frameworks indicates that outcome expectations influence health behavior, these formulations leave large proportions of behavioral variance unexplained (M. H. Becker, 1990), thus suggesting the need to identify the contributions of other motivational processes.

Self-efficacy. A desire to change does not stimulate problem solving unless one believes oneself to be capable of performing the recommended action (Bandura, 1977, 1986). Unfortunately, people often are unduly pessimistic about their capabilities. Prime examples include the many Americans with elevated cardiovascular risk factors who fail to change their diet and exercise patterns despite a desire to do so (Oldridge, 1982). Research in this large and important population dramatically illustrates the power of self-appraisal: In high-risk individuals, increases in self-efficacy following a treadmill exercise test predict

subsequent compliance with prescribed exercise routines better than do treadmill performance or electrocardiogram data derived from the test (Ewart, Stewart, Gillilan, Keleman, Valenti, et al., 1986; Ewart, Taylor, Reese, & DeBusk, 1983). Moreover, self-perceived ability to exercise prior to participating in aerobic exercise training predicts posttraining gains even after controlling for pre-treatment capability (Ewart, Stewart, Gillilan, & Keleman, 1986).

Research on the origins of self-efficacy suggests ways to enhance one's personal confidence by means of low cost, widely applicable interventions involving social modeling and graduated performance of feared activities (Bandura, in press; Ewart, 1989b, 1990). In people who fear exercise, self-efficacy can be strengthened by performing simple, safe exercise tests. By providing confidence-building interpretation of test results as part of standard medical evaluation, self-efficacy can be enhanced (Ewart, Taylor, et al., 1983). Principles of self-efficacy enhancement also can be applied to public health communications to promote participation in preventive screening (Rippletoe & Rogers, 1987).

Goal structures. Although experimental analyses of self-regulation usually examine isolated behavioral responses, epidemiologic studies of eating, exercising, or smoking show that these and other health habits belong to larger clusters of action scripts directed toward some greater goal, and that such clusters are more prevalent in some population subgroups than in others (Donovan, Jessor, & Costa, 1988). This discovery challenges self-regulation theorists to explain how action clusters are formed and how these structures might affect population responses to behavior change appeals. Contemporary social-cognitive approaches to personality provide constructs that may prove useful in addressing these questions. Recent work on personal "strivings" (Emmons, 1986), "projects" (Little, 1983), "tasks" (Cantor, Norem, Niedenthal, Langston, & Brower, 1987), and "social goals" (M. E. Ford, 1982), for example, suggests that action clusters are constituted by an individual's personal projects. These projects respond to basic tasks of living such as achieving social influence, being accepted by others, acquiring material resources, establishing intimacy, or protecting personal safety. Projects change over time as different age-graded normative tasks become critical to negotiating successive developmental phases of the life span (Caspi, 1987). For example, eating large quantities of junk foods and experimenting with tobacco, alcohol, or drugs compose a cluster that may serve an adolescent's goal of being accepted by peers (Jessor, Chase, & Donovan, 1980), whereas in an adult, behaviors composing this cluster often increase in an effort to manage job stress (Johansson, Johnson, & Hall, 1991). Positive affect is associated with the perception that important goals are being attained and that negative affect is associated with low expectations of success or with conflicts among one's various goals (Emmons & King, 1988, 1989; Ruehlman, 1985).

Projects affect the creation of self-protective action

patterns by causing people to generate self-directive goals or behavioral intentions (Fishbein & Ajzen, 1975; M. E. Ford & Nichols, 1987), together with standards for evaluating one's performance (Bandura, 1988). Directive goals embodied in personal projects guide people into activities and environments that affect their responses to behavior change inducements. Health behavior changes seen to facilitate important projects will be adopted more easily than changes that appear less compatible (Eiser & Gentle, 1988), even when the latter are viewed as desirable (outcome expectancy) and feasible (self-efficacy). For example, after a heart attack, patients are more likely to follow a rehabilitative exercise regimen if they strongly want to recover energy needed to resume a challenging career than if they are concerned with minimizing discomfort or avoiding work stress (Oldridge, 1982). Encouraging weight-loss clients to reflect on their commitments and priorities has been shown to help them integrate dietary change objectives with valued goals and thus facilitate clinic-based weight loss (S. H. Schwartz & Inbar-Saban, 1988). By surveying people's projects, public health planners can gain important insights into higher order goals that motivate a target population, and thus discover ways to make an intervention more attractive to those it is meant to serve.

In addition to developing directive goals, people formulate self-standards by which to judge the adequacy of their efforts. Attaining a goal results in self-approval and thus stimulates further goal-directed effort (Bandura, 1989). Public health campaigns can stimulate change by activating self-evaluation, but goal theories differ as to whether easy, difficult, or moderately challenging standards inspire the greatest effort (Bandura, 1988; Locke, Shaw, Saari, & Latham, 1981). It appears that the optimal level of challenge depends on the nature of the directive goal (Hyland, 1988). When the directive goal is a physical *state*, such as achieving a lower blood cholesterol level or lower body weight, comparatively easy goals (e.g., try 2% milk before switching to skim milk; lose only one pound per week) are most effective as they make attaining the desired end state easier and more certain. On the other hand, when the directive goal is to enhance a protective *skill*, such as mastering a health-promoting sport or self-control technique, moderately difficult goals should generate greater persistence as they ensure a sense of achievement and provide more informative feedback about one's capabilities than do very easy or very difficult goals (Bandura & Schunk, 1981).

Judgments concerning personal capabilities and self-goals are interactive subprocesses; directive goals and self-standards affect self-efficacy, and self-efficacy appraisals guide the selection of action strategies. This interactive view raises important questions for social-cognitive theory. For example, interventions to enhance self-efficacy may prove more effective when a person's valued projects aim at achieving mastery goals such as skill or strength enhancement than when projects serve end states such as increasing physical comfort or enjoyment (S. H. Schwartz & Inbar-Saban, 1988).

Generative Capabilities

The acts of solving a problem, formulating a goal, appraising one's capabilities, or foreseeing the consequences of behavior draw on various forms of knowledge or schemas. Cognitive schemas represent organized knowledge sets that direct one's attention to specific aspects of situations and environments, guide the encoding of experiences in long-term memory, and provide procedural routines for performing familiar tasks (Winfrey & Goldfried, 1986). Declarative knowledge schemas represent facts and beliefs about oneself, one's body, and the social and physical world, whereas procedural schemas consist of skills and rules for applying declarative knowledge (Anderson, 1983). Together, these knowledge forms comprise generative capabilities that allow one to envisage alternative goals and create novel action strategies (Linville & Clark, 1989). As enablers of motivation and problem solving, these generative capabilities constitute important mechanisms by which social and physical environments affect self-regulatory acts.

A class of procedural schemas critical to self-control was noted a century ago by William James (1890/1950), who observed that the essential act of will (self-regulation) involves "attending to a difficult object" in the form of an imagined possibility that inhibits or energizes action. Contemporary research supports this insight (Kanfer, 1980) and demonstrates that self-control is facilitated by skill in cognitively transforming distressing thoughts and aversive stimuli (McCaul & Malott, 1984). Developmental studies of children's ability to delay gratification in the face of temptation reveal that delay is related to the acquisition of attention deployment strategies used during the waiting interval, knowledge of delay rules, and intelligence (e.g., Rodriguez, Mischel, & Shoda, 1989).

Social action theory suggests that cognitive control schemas influence behavioral choices by increasing confidence in one's ability to persist in temptation avoidance. This is supported by examination of eating habits in a recent epidemiologic study (Slater, 1989). Individuals' confidence in their ability to control distressing thoughts and ruminations (cognitive control) predicted their self-efficacy for controlling eating behavior, and self-efficacy (but not cognitive control) predicted their dietary habits. Experimental studies provide further evidence that self-efficacy mediates the influences of cognitive schemas; attending to obstacles that might impair one's ability to perform an experimental task lowers self-efficacy, and lowered self-efficacy subsequently is associated with impaired performance (Cervone, 1989). Teaching attentional control techniques for pain management improves self-efficacy for pain control, which in turn is associated with increased pain tolerance (Bandura, O'Leary, Taylor, Gauthier, & Gossard, 1987).

Desire to mobilize control skills is influenced by declarative (factual) knowledge. People resort to personal illness representations (Leventhal, Meyer, & Gutman, 1980; Meyer, Leventhal, & Gutman, 1985) to interpret felt symptoms and diagnostic labels; these representations

can impair ability to appraise risk or anticipate possible consequences of health-endangering actions (Weinstein, 1988). Public health interventions can enhance action capabilities by altering inaccurate schemas and providing useful knowledge and skills. In addition to cognitive control skills, helpful procedural schemas include skills for evaluating health-relevant information (e.g., TV commercials, product labels) and reflecting on one's problem-solving efforts. For example, simply teaching people to monitor and evaluate their problem-solving progress improves the quality of solutions achieved (Kluwe & Friedrichsen, 1985), and focusing one's attention on the process of problem solving is more helpful than focusing on the final goal (Kuhl, 1985). Mentally envisaging oneself performing a chosen strategy prior to enacting it increases the probability of success (Nuttin, 1984; Wilensky, 1983).

Novel schemas are most easily assimilated when presented in the form of a story about an actor (model) who successfully confronts a problem scenario in which the instigating conditions and the actor's goals, behavior sequences, and experienced outcomes are clearly specified (Bandura & Jeffery, 1973; Winett, King, & Altman, 1989). Retention is enhanced when this material is presented following principles known to facilitate cognitive encoding and retrieval of health-relevant information (Ley, 1977). It appears that schemas involving core assumptions about personal vulnerability may be more difficult to change than schemas representing procedural routines or facts about illness (Janoff-Bulman, 1989). People are more likely to revise vulnerability schemas in response to crises and during transitions into new environments (Cantor, 1990), suggesting that risk education might target those undergoing life changes or experiencing an illness or death in their immediate social network (D. Becker & Levine, 1987).

Social Interaction Processes

Although self-regulation theorists have tended to view action capabilities as properties of the individual, a social-contextual view asserts that these abilities are also a function of an individual's close personal relationships (Ewart, 1990; McFall, 1982). When behavior changes threaten to disrupt a valued relationship, a satisfactory outcome depends on the partners' ability to collaborate effectively in problem solving; that is, success depends on partners' conjoint (as opposed to individual) social capabilities. These capabilities can be enhanced by simple, cost-effective interventions that can be widely implemented in health care settings. For example, including a cardiac patient's spouse in an exercise stress-test protocol has been shown to increase couple agreement concerning the former's physical abilities, thereby removing a significant interpersonal obstacle to exercise compliance for tertiary prevention (Taylor, Bandura, Ewart, Miller, & DeBusk, 1985). In a city clinic serving low-income Black outpatients, including a family member in brief, behaviorally specific counseling and regimen planning increased the patient's long-term compliance with antihypertensive medications, resulting in improved blood pressure con-

trol, and reduced mortality over a five-year follow-up interval (Levine et al., 1979; Morisky et al., 1983). These interventions presumably operate by altering the relevant knowledge schemas of each of the parties (e.g., demonstrating to a spouse what the patient can do) and promoting shared projects, increasing self-efficacy, and building shared commitment to a specific plan of action (Black, Gleser, & Kooyers, 1990).

To increase relationship support for self-regulation, it is necessary to clarify the origins of conjoint (relationship) competence and to determine how interpersonal processes and capabilities influence personal self-control. Research on marital communication and problem solving suggests that a relationship's competence is a function of dyadic orientation processes, defined in terms of the frequency, skill, and persistence with which both partners attempt to understand each other's goals, identify shared objectives, separate conflict over one goal or project from other relationship goals and projects, and endorse or validate each other's strivings (Gottman, Notarius, Gonso, & Markman, 1976). These activities are facilitated by engagement processes including reflective listening, efforts to distinguish a communication's intent from its felt impact, and attempts to translate general criticisms into behaviorally specific requests (Jacobson & Holtzworth-Monroe, 1986). Relationship competence is also increased by control processes, such as specifying clear and attainable goals, developing action plans, and monitoring their implementation (Jacobson & Margolin, 1979). Relationship deficits in orientation, engagement, and control competence are associated with elevated blood pressure during marital conflict in persons with essential hypertension (Ewart, Taylor, Kraemer, & Agras, 1991), and conjoint training that targets these skills reduces cardiovascular reactivity during family arguments (Ewart, Burnett, & Taylor, 1983; Ewart, Taylor et al., 1984).

Research on social support indicates that the availability of a trusted confidant (typically a spouse) appears to be the critical factor determining whether people feel they are adequately supported in coping with difficult challenges (Heller, Swindle, & Dusenbury, 1986). The analysis of relationship competence identifies interpersonal processes conducive to sustained self-regulatory support. It suggests that people will anticipate greater support for self-protective activities and feel more confident in their ability to change if they and a trusted other are able to (a) report multiple mutual goals and projects, (b) describe their relationship conflicts in terms of specific situations and behaviors, and (c) engage in collective goal-setting and monitoring (control) activities. Manipulating these relationship capabilities in studies of behavioral adherence might disclose more effective ways to increase social support for self-protective action.

Social Environmental Determinants of Self-Regulation

Social-cognitive theories explain self-regulation in terms of internal processes and transactions with one's im-

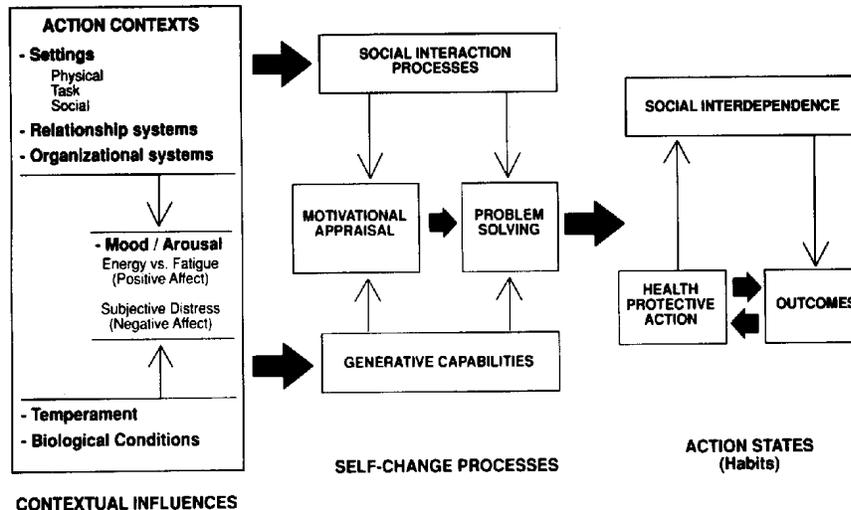
mediate milieu. A public health perspective, however, views individual self-regulation as a subcomponent of larger environmental systems. These systems create contextual influences (the third term in the host-agent-environment paradigm) that constrain or facilitate self-protective acts. A contextual model (Figure 4) thus completes the public health paradigm by indicating how environments affect self-change processes (Figure 3) to disrupt or maintain a given action state (Figure 2). The model guides social and organizational intervention to encourage personal change.

This model also challenges the dominant public health view of person-environment interaction, which is a simple mechanistic conception of biological susceptibility interacting with an environmental hazard (e.g., lung cancer risk increases synergistically in workers whose nicotine-damaged lungs are exposed to airborne asbestos fibers). Although simple mechanistic models can explain many public health risks, social action theory introduces the possibility of more dynamic, reciprocal relationships between persons and environmental contexts. Personal goals, expectations, skills, and strategies cause individuals to seek or create environments that satisfy their strivings and suit their capabilities (Emmons, Diener, & Larsen, 1986); this reciprocal conception helps explain risks that arise and persist because people actively choose environments that support health-endangering goals and plans. For example, longitudinal data from the Framingham heart disease study suggest that people tend to select marriage partners whose degree of obesity, smoking, alcohol use, and dietary habits match their own (Sackett, Anderson, Milner, Feinleib, & Kannel, 1975). In this view of interaction, contexts modify personal generative capabilities and social relations in ways that affect how people generate goals, envisage opportunities for action, and devise and execute health-relevant strategies.

Contextual determinants of action capabilities.

Public health practitioners need to know how changes in work, community, or family environments are likely to affect the individual's capacity for self-protective action. Among psychologists, interest in this question owes much to the ecological views of James G. Kelly, who has argued that individual behavior responds to normative expectations of social settings, that behavioral demands of one setting (e.g., work environment) affect behavior in other settings (e.g., family relationships), and that personal change is constrained by access to important community resources and by the behavior's compatibility with enduring communal values or practices (Trickett, 1987). Kelly was influenced by Kurt Lewin and his student Roger Barker, who noted that individual differences in behavior often were more a function of environmental variation than of differences in knowledge, attitudes, intelligence, or personality (Wicker, 1979). Others have combined behavior analysis with Marxist theory (Harris, 1979) to explain individual behavior in terms of constraints imposed by physical environments, technologies of production, and the social roles, organizational structures, and political systems to which modes of production and reproduction give rise (Biglan, Glasgow, & Singer, 1990).

Figure 4
Contextual Model Representing Self-Regulation as a Subcomponent of Larger Social and Environmental Systems



Note. The model specifies contextual influences that, by altering microsocial relationships and personal generative capabilities (self-change processes), empower or constrain the development of self-protective habits (action states).

Attempts to explain individual behavior in terms of social organization or structure have a long history in sociology and cultural anthropology (e.g., Giddens, 1979; Parsons, 1949). These literatures suggest that environmental settings and social systems affect personal behavior by channeling a person's interpretations of events, affecting one's biological condition, influencing the formation of close relationships, and interacting with physiological processes to generate mood states that bias cognition and constrain social interaction (e.g., Kohn & Schooler, 1982). Social action theory (Figure 4) assists in analyzing these influences—and person–environment interactions in general—by characterizing settings and systems in terms of the goals they activate and the personal capabilities, social interactions, motivational appraisals, and action strategies they support.

Settings, defined as the physical features of one's environment, the tasks routinely performed there, and the people composing one's proximal social milieu, influence action goals and strategies by determining access to needed material resources such as health-enhancing foods or exercise facilities (Kerr, Amante, Decker, & Callen, 1982; Oldridge, 1982), as well as energy resources in the form of information, time, and money. Health promoters have acknowledged the importance of settings by introducing health behavior change programs into the worksite (Cataldo & Coates, 1986); however, a contextual perspective suggests the importance of restructuring work settings and tasks so as to alter stressful conditions that contribute to health-damaging habits such as smoking and lack of exercise (Johansson et al., 1991).

Social relationships affect personal action by shaping physical and interpersonal environments. Relationships entail a range of benefits, expectations, and obligations that influence health-relevant goals and strategies.³ For example, the cooperation of a spouse enhances compliance with diet, smoking, and exercise interventions (Black et al., 1990; Cohen & Lichtenstein, 1990; Sallis et al., 1987) and with substance abuse treatments (Wiens & Menustik, 1983), yet relationship systems also impose social obligations that may interfere with self-protective activities (Riley & Eckenrode, 1986). Peer networks provide contacts with others who can assist with problems, enhance self-efficacy by suggesting effective strategies, and bolster self-esteem by advocating more favorable self-evaluative standards (Thoits, 1986). These relationships also provide social models whose behavior facilitates or inhibits action patterns; consumption of alcohol or tobacco by heavy drinkers or smokers increases in the presence of model who is drinking or smoking (Collins & Marlatt, 1981; Kniskern, Biglan, Lichtenstein, Fry, &

³ Social roles and accompanying norms of conduct often are invoked to explain how social systems influence individual behavior. Role theory has been subject to a number of critiques (Lyman & Scott, 1975; J. F. Scott, 1971), including challenges to the simplistic notion that society supplies the roles to which actors adapt as best they might and to the questionable assumption of strong normative consensus about the behaviors the individual must execute. To quote Giddens (1979), "Social systems are not constituted of roles, but of (reproduced) practices" (p. 117); depending on one's position in the system, these practices entail a range of perogatives and obligations that an actor may decide to activate or carry out.

Bavry, 1983). Similar effects have been demonstrated in eating behaviors (Rosenthal & McSweeney, 1979).

Organizational structures at the level of government, economic, educational, and health care systems channel individuals' goals, expectations, and strategies in diverse ways (Altman, 1990; Winett et al., 1989). Systems of production, distribution, and promotion, together with government regulatory policies, affect exposure to settings, products, and messages that influence health choices (Gorn & Goldberg, 1982; Wadden & Brownell, 1984; Warner, 1986).

Physical settings and social systems both affect and interact with biological structures and processes within the person to create intrapersonal contexts that influence goals and generative capabilities. Physical and social environments modify cognitive skills by affecting the growth of the nervous system and by providing social experiences that change the ways children, adolescents, and adults perceive contingencies, appraise their abilities, and solve problems (Hanna et al., 1990; Nicholls & Miller, 1984). Biologically based differences in temperament apparent at birth and persisting over the life span influence personal preferences for social interaction, tolerance for novel stimuli, intensity of activity, and emotional arousability; these differences contribute to differential socialization experiences affecting acquisition of health-relevant goals, expectations, and skills (Goldsmith et al., 1987; Kagan, Reznick, & Snidman, 1988).

Social and biological influences combine to generate *mood states*, which reflect combinations of energy level or positive affect, and subjective distress or negative affect (Watson & Pennebaker, 1989). Emotional arousal affects attention deployment; under high arousal, people are less able to detect stimuli, attend to their own behavior, or appraise the long-term consequences of personal decisions (Jarvis, 1982). Mood and arousal also influence the type of health information encoded into memory, the degree to which it is actively processed, and ability to retrieve it later (Bower, 1981; Leventhal, 1970; Petty & Cacioppo, 1986). Moreover, emotional expression or inhibition may affect behavioral control; for example, anger inhibition in response to provocation has been shown to increase subsequent alcohol consumption by social drinkers (Marlatt, Kosturn, & Lang, 1975). Emotional distress also can impair interpersonal problem-solving capabilities, thereby affecting relationship support for personal change.

Social Contexts and Empowerment for Self-Change

Contextual influences determine the success of interventions to promote self-protective behavior. Social action theory provides a useful taxonomy for organizing intervention strategies, as shown in Table 1. Behavioral research has focused on techniques that facilitate desired action states; far less is known about the ways in which contextual factors influence self-change processes to decide the fate of nascent self-control. This is unfortunate, as interventions to promote habit changes are difficult to implement and sustain without broader social, institutional, or political intervention (Winett et al., 1989).

This concern is evident in the field of community psychology, in which investigators have shown increasing interest in "phenomena of empowerment" (Rappaport, 1987). Empowerment is at once an individual and a social construct, referring both to a sense of personal control, mastery, and power to effect change, and to a group's or organization's ability to control community resources, engage in collective decision making, and achieve shared goals (Chavis & Wandersman, 1990). Individual empowerment is seen to flow from collective empowerment; political arrangements that empower groups by giving them ownership of material resources, information, and decision-making authority foster individual empowerment of group members by providing direct experience in organizing people, identifying resources, and developing strategies for achieving goals (Zimmerman & Rappaport, 1988).

A connection between the two types of empowerment is suggested by data showing that people who take an active role in community organizations score higher than do less-involved peers on such empowerment indexes as internal locus of control, belief that people can influence political decisions, self-esteem, and personal sense of mastery (Kieffer, 1984; Zimmerman & Rappaport, 1988). Although the direction of causation remains to be clarified, the theory is significant in specifying organizational structures that may affect an individual's ability to take self-protective action and in generating guidelines for organizing groups and effecting political and institutional changes to support self-protective behavior (Christenson & Robinson, 1989).

Social action theory aids this task by specifying mediating mechanisms linking organizational structures to personal health. For example, community empowerment will affect individual community members differently, according to their personal projects, generative capabilities, exposure to social models, and the availability of supportive feedback (Bandura, 1986). Moreover, social action theory suggests that empowerment is not a unitary construct; organizational forms may differ with respect to the number and type of personal goals, capabilities, and action strategies they enhance. Participating in an organization with a rigid ideology and hierarchical leadership structure may foster one's sense of social empowerment (e.g., commitment to the organization's goals and confidence in its political influence) yet fail to enhance individual empowerment defined as capacity for self-protective action (Pargament et al., 1987). Other structures could increase a sense of self-mastery without building the conviction that through collective action people can shape their social destiny or might foster some personal action components (e.g., commitment to self-change goals) at the expense of others (e.g., self-change skills).

Individual empowerment should be enhanced by organizations that (a) encourage their members to identify and pursue tasks that match their personal goals, (b) permit forms of participation that match members' capabilities and allow them to become involved in an incrementally demanding manner, and (c) reward members

Table 1

Interventions to Facilitate Health Protective Action States, Activate Self-Change Mechanisms, and Create Contexts That Support Sustained Action in Modifying Diet, Obesity, Exercise, Smoking, and Alcohol Use

Intervention	References*
Facilitating desired action states	
Stimulus control Introduce/remove environmental cues ^{1,2}	1. Brownell, Stunkard, & Albaum, 1980 2. Kazdin, 1984
Self-monitoring Compare personal performance against a monitored behavioral standard ^{2,3,4}	3. Martin et al., 1984 4. Scott, Denier, Prue, & King, 1986 5. Elder, 1987
Reinforcement Provide desired short-term consequences to support health-enhancing behavior; remove undesired consequences ^{2,5} Provide feedback, monetary, material, or social rewards ^{2,3,5,6,7,8}	6. Ewart, Li, & Coates, 1983 7. Klesges, Vasey, & Glasgow, 1986 8. Brownell, Marlatt, Lichtenstein, & Wilson, 1986
Aversive control Aversive counterconditioning of addictive behavior ⁹ Response cost (e.g., fines, loss of advance deposit) ^{2,5,10}	9. Wiens & Menustik, 1983 10. Bowers, Winett, & Fredriksen, 1987 11. Ewart, 1990
Behavioral restructuring Interrupt early components of problem scripts; integrate desired scripts with existing routines; coordinate with scripts of intimate others ^{2,11,12}	12. Ewart, 1989a
Activating self-change processes	
Problem solving Identify dysfunctional strategies; adopt action orientation; generate and evaluate alternative strategies; formulate action plan ¹³⁻¹⁵	13. Hanna, Ewart, & Kwiterovich, 1990 14. Kuhl, 1985 15. D'Zurilla, 1986
Motivational appraisal Outcome expectancies: Decisional balance sheet procedures ¹⁶⁻¹⁸ Self-efficacy expectancies: Graduated performance and persuasion ¹⁹ Goal structures: Project analysis; values clarification; goal setting ^{2,20,21}	16. Janis & Mann, 1977 17. Velicer, DiClemente, Prochaska, & Brandenburg, 1985 18. Marlatt & Gordon, 1985 19. Ewart, 1989a 20. Little, 1983 21. S. H. Schwartz & Inbar-Saban, 1988
Generative capabilities Teach self-control techniques ¹⁸ Provide declarative and procedural action schemas via direct or symbolic (e.g., TV) modelig ²²	22. Winett, King, & Altman, 1989 23. Botvin, Baker, Botvin, Filazzola, & Millman, 1984
Social interaction processes Peer pressure resistance training ²³ Family self-efficacy training ²⁴ Family problem-solving training ²⁵	24. Taylor, Bandura, Ewart, Miller, & DeBusk, 1985 25. Ewart, Taylor, Kraemer, & Agras, 1984
Creating action contexts	
Settings Provide needed facilities, time, equipment, foods, personnel ^{26,27}	26. King, Carl, Birkel, & Haskell, 1988 27. Levy, Matthews, Stephenson, Tenney, & Schucker, 1985
Relationship systems Develop support groups; implement buddy systems ^{28,29}	28. Janis, 1983 29. Cohen & Lichtenstein, 1990
Organizational structures Community organization and collective action to change laws and policies affecting work environment; promote healthier food standards; control availability and advertising of health-endangering products ³⁰⁻³²	30. DiFranza, Norwood, Garner, & Tye, 1987 31. Flay, 1987 32. Warner, 1986 33. Goldstein, Niaura, Follick, & Abrams, 1989
Biological conditions Pharmacologic intervention to alleviate withdrawal symptoms (e.g., nicotine gum) ³³	34. Ewart et al., 1987 35. King, Winett, & Lovett, 1986
Mood/Arousal Relaxation training ³⁴ Stress management training ³⁵	

* References describe the techniques and document their effectiveness.

for their contributions. These conditions should be facilitated by a flexible leadership structure, open sharing of information and decision making, moderate group size, and collective control of necessary resources (Zimmerman & Rappaport, 1988). Research comparing effects of different organizational structures on self-regulatory subprocesses represents a vital yet undeveloped zone of contact between social-cognitive theory, community psychology, and the field of public health.

Social Contexts and Stages of Self-Change

Social-contextual analysis also has implications for the view that habit changes occur in a sequence of qualitatively distinct behavioral stages (Horn & Waingrown, 1966; Kristeller & Rodin, 1984; Prochaska & DiClemente, 1983). A stage conception is useful if proposed stages reflect different functional mechanisms or processes of self-change. The problem is to identify the critical mechanisms, influences that activate them, and conditions that cause people to move from one behavioral stage to the next. Social action theory specifies mechanisms involving motivational appraisal and problem solving, indicates the order in which they are activated (e.g., appraisal prior to problem solving), and identifies generative capabilities and proximal social interaction processes that must be present before motivation can generate sustained action. Data from studies of smoking cessation suggest that smokers proceed from contemplation to active cessation and abstinence as envisaged here (Prochaska, Velicer, DiClemente, & Fava, 1988).

What propels people from stage to stage? The model's contextual dimension suggests that social and biological contexts play a critical determining role. Social settings and relationships activate health goals (e.g., parents worry that their smoking may harm their young child), provide helpful action schemas (e.g., a co-worker's successful abstinence provides a model of how to quit), and facilitate the modification of problem scripts (e.g., a spouse agrees to help). Biologic conditions and mood states (e.g., worry about illness symptoms) also activate health goals and may facilitate the implementation of action schemas (e.g., reduced work stress makes it easier to stop smoking). Moreover, contextual influences determine longer term success. For example, a stressful environment, the presence of other smokers, and unpleasant mood states related to nicotine craving and withdrawal are major contextual obstacles to prolonged nonsmoking (Marlatt, Curry, & Gordon, 1988). Indeed, a social contextual view suggests that maintenance may best be understood as a process of identifying and altering physical, social, and biological contexts that undermine motivational and problem-solving mechanisms of self-change.

Conclusions

When it is not feasible to remove health threats from human environments, prevention must strive to promote individual self-protective activity by altering laws and policies, rendering environments conducive to personal action, and educating the public. Social action theory

(Figure 4) offers an integrative action schema for defining public health goals and identifying modifiable personal and social-contextual influences that can be activated to encourage self-protective activities. The framework is designed to facilitate interdisciplinary collaboration in public health research by coordinating the perspectives of psychology with perspectives of the biological, epidemiological, and social-organizational sciences.

Social action theory develops new agendas for a public health psychology. Social contextual analysis raises questions concerning the role of social interdependence and interaction in self-regulation and proposes a number of testable hypotheses about processes that mediate connections between environmental changes and personal behavior. To address these questions effectively, it will be helpful for psychologists to receive public health training and to collaborate in research with investigators from other social science disciplines (DeLeon & Pallak, 1982; Matthews & Siegel, 1987). By stimulating this collaboration, a social-contextual theory of action provides new directions to advance psychology as a scientific discipline while more widely benefiting the world's peoples.

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