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Cultural adaptation of an evidence-based nursing intervention to improve medication adherence among people living with HIV/AIDS (PLWHA) in China

Ann B. Williams, RN, EdD [Professor],

School of Nursing, University of California Los Angeles, 10880 Wilshire Blvd, Suite 550, Los Angeles, CA 90024, 310 285 0303

Honghong Wang, RN, PhD [Professor],

School of Nursing, Central South University, Yuelu Mountain, Changsha, Hunan, China

Jane Burgess, ACRN, MS [National Program Manager],

QUERI-HIV/Hepatitis, VA Greater Los Angeles Healthcare System, 12000 Wilshire Blvd., Los Angeles, CA 90024

Xianhong Li, RN, PhD [Assistant Professor], and

School of Nursing, Central South University, Yuelu Mountain, Changsha, Hunan, China

Karina Danvers, MA [Director]

Connecticut AIDS Education and Training Center, Yale School of Nursing, P.O. 9740, New Haven, CT 06610

Ann B. Williams: awilliams@sonnet.ucla.edu; Honghong Wang: Honghong_wang@tom.com; Jane Burgess: Jane.Burgess@VA.gov; Xianhong Li: Xianhong_li228@hotmail.com; Karina Danvers: Karina.Danvers@yale.edu

Abstract

BACKGROUND—Adapting nursing interventions to suit the needs and culture of a new population (cultural adaptation) is an important early step in the process of implementation and dissemination. While the need for cultural adaptation is widely accepted, research-based strategies for doing so are not well articulated. Non-adherence to medications for chronic disease is a global problem and cultural adaptation of existing evidence-based interventions could be useful.

OBJECTIVES—This paper aims to describe the cultural adaptation of an evidence-based nursing intervention to improve medication adherence among people living with HIV/AIDS and to offer recommendations for adaptation of interventions across cultures and borders.

SITE—The intervention, which demonstrated efficacy in a randomized controlled trial in North America, was adapted for the cultural and social context of Hunan Province, in south central China.

SOURCES OF DATA—The adaptation process was undertaken by intervention stakeholders including the original intervention study team, the proposed adaptation team, and members of a Community Advisory Board, including people living with HIV/AIDS, family members, and health care workers at the target clinical sites.

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PROCEDURES—The adaptation process was driven by quantitative and qualitative data describing the new population and context and was guided by principles for cultural adaptation drawn from prevention science research.

RESULTS—The primary adaptation to the intervention was the inclusion of family members in intervention activities, in response to the cultural and social importance of the family in rural China. In a pilot test of the adapted intervention, self-reported medication adherence improved significantly in the group receiving the intervention compared to the control group ($p=0.01$). Recommendations for cultural adaptation of nursing interventions include 1) involve stakeholders from the beginning; 2) assess the population, need, and context; 3) evaluate the intervention to be adapted with attention to details of the original studies that demonstrated efficacy; 4) compare important elements of the original intervention with those of the proposed new population and context to identify primary points for adaptation; 5) explicitly identify sources of tension between intervention fidelity and cultural adaptive needs; 6) document the process of adaptation, pilot the adapted intervention, and evaluate its effectiveness before moving to dissemination and implementation on a large scale.

Keywords

Cultural adaptation; Nursing intervention; Medication adherence; HIV/AIDS; China

1. Introduction

1.1 Cultural adaptation of efficacious nursing interventions

In response to the growing call for implementation and dissemination of evidence-based nursing interventions, nurse researchers face the challenge of building a portfolio of interventions that have demonstrated both efficacy and effectiveness. To meet this challenge, thoughtful and articulate descriptions of the process of moving from efficacy to effectiveness to implementation are imperative. Adapting nursing interventions to suit the needs and culture of a new population (cultural adaptation) is an important early step in the process of implementation and dissemination.

Evidence-based nursing interventions are those which have been evaluated in high quality research studies which were conducted according to established scientific principles for conduct of research. Under these conditions, interventions that demonstrate a significant impact on outcomes of interest can be considered “efficacious”. However, successful implementation and dissemination of an efficacious intervention into clinical practice requires an initial demonstration of the “effectiveness” of the intervention (Flay et al., 2005). Intervention effectiveness is established through studies conducted under real world conditions with fidelity to the original intervention and sound measures of the outcome (Flay et al., 2005, Kellam and Langevin, 2003).

Progress in conducting effectiveness research is hampered by the lack of research on the process of adapting interventions that demonstrated efficacy under the highly controlled conditions of clinical trials to the real world clinical context. Nowhere is the adaptation effort more important than when seeking to implement an intervention in a country other than that where it was developed and first tested.

The goal of adaptation is to maintain the efficacy of the intervention by preserving the core features that account for the intervention’s success while delivering an intervention that is responsive to the new community and cultural context. Fidelity, or the extent to which delivery of the intervention adheres to the original study protocol, requires replication of the core concepts and mechanism of effect (Castro et al., 2010). When an intervention is delivered to a new population, tension between intervention fidelity and the need to adapt

the intervention to suit the needs and culture of the new population is inevitable (Bell et al., 2007, Castro et al., 2004).

Adaptation of evidence-based interventions may require changes in content and the form of delivery (Castro et al., 2004). Surface structure changes to interventions are alterations that match the materials and the methods of the intervention to the characteristics of the population without changing its essential core components (Osuna et al., 2011). Although strategies for identifying core components of interventions are largely untested (Elliott and Mihalic, 2004), there is general agreement on a range of prerequisites for successful adaptation. These include 1) knowledge about the population and context for which the adaptation is intended, 2) acceptability of the intervention by the population, 3) maintenance of core elements, 4) a systematic approach to reducing discrepancies between the intervention as tested and the needs and sensibilities of the new population, and 5) documentation of the adaptation (Castro et al., 2004, Solomon et al., 2006).

A structured framework organizes the many individual tasks required to adapt interventions. Prevention science researchers have proposed several frameworks for organizing adaptation activities which are relevant for nursing researchers (Kumpfer et al., 2008, McKleroy et al., 2006, Wingood and DiClemente, 2008). While the details of the frameworks differ, all are stage models and all include initial assessment and information gathering, identification of contextual characteristics that could influence intervention effect, some type of community or patient feedback, and an organized approach to making the adaptive changes. An important goal is to identify sources of potential mismatch between the original study context and the new context. These potential mismatches, which can be categorized as group characteristics, intervention delivery characteristics, and administration or community factors, then make up the primary targets for cultural adaptation (Castro et al., 2004).

This paper describes the cultural adaptation of a nursing intervention, including the steps taken to adapt the intervention, and offers recommendations to guide the cultural adaptation of nursing interventions preliminary to implementation and dissemination studies.

1.2 A nursing intervention to improve adherence among people living with HIV/AIDS

Non-adherence to medications for chronic disease is a world-wide challenge (DiMatteo, 2004, Sabate, 2003) which nurses often are called to address. ATHENA (Adherence Through Home Education and Nursing Assessment) is an evidence-based home nursing intervention that demonstrated efficacy in a randomized clinical trial (RCT) in northeastern United States. ATHENA aims to improve medication adherence among patients for whom antiretroviral (ARV) therapy for HIV infection is prescribed. The intervention is guided by the pedagogical theory of Paolo (Freire, 1986) and led by nurses who facilitate a self-directed process in which patients identify individual and social factors which influence their success with adherence to medication regimens and which, when recognized, can lead to more effective self-management of medication (Williams et al., 2005).

Participants in the ATHENA RCT were 171 adults, the majority of whom had a past or current history of substance abuse. Subjects were randomly assigned to receive the intervention or usual care. Adherence declined over time in both groups, but at each time point after baseline, a larger proportion of the subjects in the intervention group demonstrated adherence greater than 90% compared to the control group (Extended Mantel-Haenszel Test: 5.80, $p=.02$). There was also a statistically significant association between greater than 90% adherence and an undetectable HIV-RNA over time ($p=.03$) (Williams et al., 2006).

The ATHENA study was one of the earliest rigorous, controlled trials of an adherence intervention targeted to a vulnerable U.S. population with a high prevalence of substance abuse and mental illness. It also is one of only 8 adherence interventions identified by the U. S. Centers for Disease Control Prevention Research Synthesis project as a good evidence-based behavioral intervention (EBI), representing one of the “strongest HIV behavioral interventions in the literature to date which have been rigorously evaluated and have demonstrated efficacy in reducing HIV viral load or improving HIV medication adherence behaviors ...” (Charania, 2010).

1.3 The adaptation context: AIDS treatment adherence in China

Since HIV infection first was identified in 1989 in Yunnan Province, HIV has spread rapidly and widely across China. At the end of 2009, there were an estimated 740,000 people with HIV/AIDS in China (Wang et al., 2010). In response, the government launched China CARES, which provides free ARV for PLWHA throughout the country. However, while ARV has a profound and positive effect on the lives of people infected with HIV, it is widely accepted that rigorous adherence to therapy is crucial to successful outcomes of ARV (de Boer et al., 2010, Lima et al., 2009, Nieuwkerk et al., 2010).

The China CARES program is bringing ARV to many low-income people living with HIV/AIDS. However, the extremely rapid initiation of the ARV distribution system precluded attention to monitoring and supporting patient adherence to ARV. As a result, there are grave concerns that adherence has been inadequate and that without effective interventions to improve adherence, viral resistance to the commonly used and most cost-effective medications soon will be widespread (Li et al., 2005).

2. Objectives

While the need for cultural adaptation is widely accepted, research-based strategies for doing so are not well articulated (Bell et al., 2007). In particular, there are few published studies or reports to guide the process of adapting efficacious nursing interventions preliminary to effectiveness and implementation studies. Therefore, the purpose of this paper is to describe the adaptation of a theoretically driven nursing intervention which improved medication adherence in a randomized clinical trial conducted in the United States, to the cultural and social context of south central China, including a pilot test of the adapted intervention, and to offer recommendations for adaptation that might be useful across cultures and geographic borders. The new population which will receive the adapted intervention is patients living with HIV/AIDS in Hunan, China, and receiving treatment from the Hunan China CARES clinical program. This article includes a description of the steps taken to adapt the intervention, preparatory to an effectiveness study of the adapted intervention.

3. Methods

3.1 Site and Target Population

The adapted ATHENA intervention will be delivered to patients of the Hunan China CARES clinical program. Hunan Province is the 11th largest province of China, located in the southeast, on the middle reaches of the Yangtze River. Social characteristics of Hunan underlying its expanding HIV/AIDS epidemic primarily include injection drug use and commercial sex work. According to data from national HIV surveillance sites in Hunan, HIV prevalence among drug users increased from 0.5% in 1998 to 28.6% in 2005. HIV prevalence among female sex workers, which was 2.5% in 1998, was 10.8% by 2004. In Hunan, China CARES provides clinical evaluation and free medication to HIV-infected individuals at over 30 sites throughout the province. Patients attending these clinics are poor

and primarily rural residents. Medications are dispensed to patients by clinic nurses on a monthly schedule.

Approval for this project has been provided by the Hunan Centers for Disease Control, Xiangya School of Medicine, and University of California Los Angeles.

3.2 Sources of data

Preliminary to designing an adaptation strategy, information gathering across a broad platform of data sources is essential (Castro et al., 2010, Osuna et al., 2011, Wingood and DiClemente, 2008). In order to capture a broad spectrum of perspectives and data sources, we collected and reviewed both quantitative and qualitative data. Quantitative data were available from two surveys conducted by our team prior to beginning the adaptation process. (Wang et al., 2008, Wang et al., 2010).

Data also were available from a qualitative study of HIV-associated stigma conducted by our team (Li et al., 2011) and from discussions with a range of stakeholders comprising the original intervention study team, the proposed adaptation team, and members of a Community Advisory Board, including PLWHA, family members, and health care workers at the target clinical sites.

3.3 Data collection

Data collection and analysis methods for the quantitative surveys have been described in detail elsewhere (Wang et al., 2008, Wang et al., 2010). Briefly, subjects for both surveys were recruited from China CARES treatment sites and data were collected in face-to-face structured interviews conducted at the time of a regularly scheduled clinic visit. The interviews addressed medication adherence, knowledge regarding HIV treatment, and social and demographic characteristics of the subjects. The interviews were conducted by trained research assistants (graduate nursing students) in Mandarin Chinese or local dialect when necessary. Informed consent was obtained and both surveys were approved by the Human Subjects Research Review Committee of Yale School of Nursing and by the Research and Technology Department of Central South University in Changsha, Hunan, China. All subjects had a confirmed diagnosis of HIV infection and were receiving ARV therapy at the time of the interviews.

Information gathered in a qualitative study of stigma conducted with the target population also informed the adaptation process. Data collection and analysis methods for that study have been described in detail elsewhere (Li et al., 2011). Briefly, subjects were purposively recruited from one China CARES site and informed consent was obtained. Data were collected in 16 individual semi-structured interviews and one focus group. The semi-structured interview schedule comprised a list of open-ended questions focused on 4 areas: illicit drug use, living with HIV, perceptions of stigma, and respondents' interpretation of the relationship between stigma associated with drug use and that associated with HIV infection. The interviews and focus group were conducted by nurse-researchers in Mandarin Chinese or local dialect. Audio recordings and field notes were used to document the discussions. The study was approved by the Institutional Review Committee of the School of Nursing of Central South University, Changsha, Hunan, China.

Finally, information provided during discussions with the original intervention study team, the proposed adaptation team, and members of the Community Advisory Board contributed to the initial assessment. The discussions were documented in meeting minutes and team reports.

3.4 Analysis

For the purpose of culturally adapting the ATHENA intervention, data gathered from the sources described above (section 3.3) were reviewed and discussed by the study team. A working group consisting of the original study team, the proposed adaptation team, and consultants with experience working in China was convened. The working group reviewed all material relevant to the intervention, identified “core elements” of the intervention which were considered essential and therefore not to be changed, noted cultural mismatches between the original context and the target context, and proposed a format for the adapted intervention. The working group met in person in New Haven, CT; in Changsha, Hunan, China; and via electronic communication throughout the course of the study. The proposed adapted intervention was presented to the Community Advisory Board in Hunan and additional changes were made based on the Board’s feedback.

The process described above went smoothly. The discussion regarding the feasibility of including HIV positive individuals on the intervention team as peer educators was extensive. The Chinese partners expressed concern that it would be difficult to find individuals willing to do this work in view of the stigma associated with AIDS in the local community and suggested substituting medical students in this role, while members of the U.S. original intervention team felt that the peer educators were an essential component of the intervention and that they could not be replaced by medical students. In the end, the Chinese team succeeded in identifying two outstanding HIV positive peer educators who were eager to participate in the project.

4. Results

4.1 Need for an intervention in the target population

The preliminary cross-sectional surveys in Hunan and neighboring provinces confirmed that from 20%– 66% of PLWHA for whom ARV was prescribed did not adhere to their medication regimen (Table 1). Reasons given for lack of adherence included forgetfulness, being away from home, being busy with work or family responsibilities, and concerns about side effects of the medications. Limited knowledge and lack of skill in medication management were also noted (Wang et al., 2008, Wang et al., 2010)

4.2 Characteristics of the target population and site

The preliminary cross-sectional surveys in Hunan and neighboring provinces (Table 1) revealed that the target population was predominantly male, rural, middle-aged, and married or cohabiting with a partner. The population was very poor with limited education. Most (84%) lived in a family household and the prevalence of current injection of heroin ranged from 8 – 66%.

The key issues highlighted by the qualitative data were the importance of family in the social and cultural context of rural Hunan and the persistence of social stigma associated with AIDS (Table 2). Multiple sources emphasized that the families of Chinese AIDS patients are an integral part of the experience of living with HIV/AIDS. Families were reported to bear responsibility for caring for patients, while patients were considered responsible for preserving the honor of the family, which often meant hiding their HIV status (Li et al., 2011).

Family concerns were closely linked to social stigma. Patients and families alike worried that neighbors in their small rural villages would learn of the diagnosis and ostracize the family. The fear of discovery was identified as a reason for missed medication doses and for refusing services such as home visits from a nurse. Other obstacles to the proposed

intervention included the difficulty of moderate to long distance travel in rural Hunan and the low level of HIV/AIDS knowledge on the part of most people.

4.3 Potential Mismatches

When adapting an efficacious intervention for implementation and dissemination, context is crucial. Differences between the characteristics and culture of the original population and the new population and culture should be identified and addressed (Castro et al., 2004). In the case of adapting the ATHENA intervention for use in Hunan Province, significant similarities and differences were identified (Table 3). Similarities included the prevalence of injection drug use, poverty, limited education, and social stigma associated with both HIV infection and injection drug use.

The major differences between the North American and the Chinese context were the central role of the family in the lives of PLWHA and the emphasis on communal responsibility as a cultural value. In the North American study, family participation was welcome, but rarely occurred. In contrast, because Chinese patients were tightly linked to their families, it was clear that the intervention would need to be adapted to more fully include family participation in intervention activities. Thus, the culturally adapted intervention was more consistent with a family-centered approach than the original intervention.

Other differences were of degree rather than of kind. For example, although patients at both the original and the target sites were poor in relation to their respective society, the Chinese were much poorer. The Chinese patients also were less educated and faced more overt discrimination as a result of their HIV infection than their North American counterparts.

The intervention delivery team and system is of critical importance. Because the HIV epidemic in China is younger than in North America, the Chinese nurses had less experience managing patients on ARV and therefore felt less confident counseling patients. The adapted intervention needed to address the need for education on the part of patients, families, and health care workers to a greater extent than the original intervention.

Table 4 summarizes the adaptive changes made based on the data and as a result of a collaborative and iterative process that included the original study team, the Chinese study team, and the Chinese stakeholders. Like the original intervention, the culturally adapted intervention was a home nursing intervention delivered by a nurse and peer educator team in a series of home visits. The culturally adapted intervention took a more deliberate and structured approach to including the family, to providing HIV education, and to addressing stigma.

4.4 Pilot test of the adapted intervention

The adapted intervention is being pilot tested in a randomized clinical trial. One hundred fourteen (114) patients who self-reported poor adherence to ARVs (N=57) or to pre-ARV medications (N=57) between July 2010 and August 2011 have been randomized to receive the adapted intervention or usual care. The pilot test, which includes a 12 month follow up data collection point, has not been completed. However, all subjects in the experimental group have received the adapted intervention and the 6 month data collection is complete. Analysis of the data at 6 months suggests a positive effect of the adapted intervention on self-reported medication adherence. There were no significant differences in adherence at baseline. At 6 months, 10% of subjects in the control group compared to zero percent in the intervention group reported adherence under 80% of prescribed doses. This difference is statistically significant ($p=0.01$; Mantel Haenszel).

5. Discussion

As this study demonstrates, successful cultural adaptation of a nursing intervention is a planned, organized, iterative, and collaborative process (Castro et al., 2010). Although strategies for conducting a cultural adaptation are not standardized, some recommendations can be made based on the experience of adapting a nursing intervention developed in urban North America to rural China. The following recommendations are offered as a starting point for further discussion.

1. Involve stakeholders from the beginning and throughout the process. Include members of the team that developed and studied the original intervention as well as stakeholders associated with the new population and context. These stakeholders include the population who will receive the intervention, the professionals who provide and administer services to the population, and the individuals who will be charged with delivering the intervention.
2. Working with stakeholders, assess the need for an intervention, the characteristics of the population, the cultural context, and the administrative and community or administrative characteristics that might affect delivery of the intervention. Begin the assessment by reviewing existing data, both quantitative and qualitative; then enhance the assessment with additional surveys and interviews as needed.
3. Evaluate the proposed intervention to be implemented: How strong is the efficacy data; how many trials were conducted? Does the intervention target the outcome of interest? What are the core elements that can't be changed without compromising fidelity to the theoretical underpinnings of the intervention?
4. Create a table comparing important elements of the original intervention with those of the proposed new population and context. Working with stakeholders, determine where adaptations will be needed, assessing both feasibility of the changes and potential impact of the proposed changes on the intervention's effect.
5. Having identified the primary targets for adaptation (Castro et al., 2004), create an organized and detailed description of the adapted intervention for review by the stakeholders. Be prepared for the dynamic tension between fidelity and adaptation and be specific about any compromises made.
6. Finally, document the process of adaptation from the beginning, pilot the adapted intervention with the new population, and evaluate its effectiveness in a larger trial before moving to dissemination and implementation on a large scale.

The practice of nursing increasingly relies on evidence-based interventions to improve the health of individuals and populations (Conn and Groves, 2011). Successful dissemination and implementation of evidence-based nursing interventions requires both complete and detailed reports of the original efficacy studies (Conn and Groves, 2011) and thoughtful, organized, and explicit strategies to adapt interventions to new cultural contexts without losing the elements responsible for the intervention's impact (Castro et al., 2004). The work of describing the process of moving from efficacy to effectiveness to implementation has only just begun. In a diverse world, cultural adaptation will remain essential.

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What is already known?

Individual, social, and cultural factors influence the effectiveness of evidence-based nursing interventions when they are implemented in real world settings.

What does this paper add?

Based on the experience of adapting an evidence-based intervention, the paper provides recommended guidelines for the cultural adaptation of nursing intervention prior to implementation and dissemination.

Table 1

Data from preliminary surveys of the target population

	(Wang et al., 2008) N=308 April–July 06	(Wang et al., 2010) N=116 July 07–April 08
Subject characteristics		
Male	193 (63%)	97 (84%)
Mean age	41 years (Range 18, 73)	37 years (Range 24, 54)
Rural resident	244 (79%)	Not available
Mean annual income	861 Yuan (individual) (137 USD)	7147 Yuan (household) (1,135 USD)
Married or cohabiting	210 (68%)	58 (50%)
Less than high school education	258 (84%)	85 (73%)
History of injection drug abuse	Not available	116 (100%)
Current injection drug abuse	25 (8%)	77 (66%)
Recruitment sites	7 Treatment sites in Hunan, Hubei, & Anhui Provinces	3 Treatment sites in Hunan Province
Prevalence of non adherence (Number and percent of subjects self-reporting having missed at least one dose of medication in the past 7 days)	64 (20%)	77 (66%)
Conclusions	Non adherence was associated with current heroin use and failure to use reminder strategies	Home visits and telephone calls improved adherence, quality of life, and depressive symptoms.

Table 2

Key qualitative information

Finding	Source of the information
Family context	
Family always knows the patient's diagnosis.	Community Advisory Board
Lack of family understanding about HIV transmission affects the care and treatment of the patient.	Community Advisory Board
Family members are worried about neighbors learning that a member is HIV-infected. This anxiety affects patients' willingness to take medication and to participate in the intervention.	Community Advisory Board
Families have a responsibility to care for sick family members.	Li's study of stigma (Li et al., 2011)
Patients feel a responsibility to maintain the honor of the family.	Li's study of stigma (Li et al., 2011)
Environmental context	
Travel to homes in rural villages is limited by long distances and muddy roads.	Chinese adaptation team
Most Chinese patients have very limited contact with physicians and there are no well defined systems for patients to report side effects or ask questions.	Chinese adaptation team
Social context	
Stigma associated with HIV is extremely prevalent and severe.	Community Advisory Board; Chinese adaptation team; Li's study of stigma (Li et al., 2011)
Stigma associated with injection drug use amplifies HIV-associated stigma.	Li's study of stigma (Li et al., 2011)

Table 3

Potential matches and mismatches; adapted from (Castro et al., 2004)

	Original intervention (Williams et al., 2006)	Proposed adaptation
Group Characteristics		
Language	English/Spanish	Mandarin/Local Dialect
Ethnicity	Diverse U.S. (European, African, and Hispanic)	Han Chinese
Economic status	Lower U.S. income level	Very poor
Educational level	Majority high school graduates	Majority non high school graduates
HIV risk	Majority history of injection drug use	Majority history of injection drug use
Treatment status	Majority over a year of treatment	Majority beginning treatment
Intervention delivery characteristics		
Staff	Nurses and peer educators highly experienced in HIV/AIDS care	Less experienced nurses and peer educators
Community context		
Environment	Urban Transportation easily available	Mixed urban/rural Transportation difficult, time consuming
Family structure	Many broken families	Extremely strong
Culture	Emphasis on individual responsibility	Emphasis on family responsibility
HIV-related stigma	Moderate	High
Injection drug use related stigma	High	High

Table 4

Proposed adaptive changes to the ATHENA intervention for the Hunan cultural context

THEORETICAL FRAMEWORK (Freire, 1986)		
	Core element	Adaptation for Hunan cultural context
Stage 1: Listening	Identification of the patient's priorities through careful listening.	<i>Inclusion of family</i> in discussion and planning.
	Identification of the context of the patient's life.	Assessment of patient <i>and family</i> context and <i>level of HIV treatment knowledge</i> .
Stage 2: Participatory dialogue	Discovery of key concepts reflective of patient's central concerns.	<i>Query family regarding family's concerns, including fear of discrimination from neighbors.</i>
	Problem-posing and critical thinking about identified concerns.	<i>Provide information and educational materials to patients and families, with an emphasis on how HIV is and is not transmitted and on the benefits and side effects of ARV.</i>
	Identification of problems in relation to adherence.	
	Syntheses and preparation of written and visual materials which symbolize the concerns.	<i>Include the family in all problem- posing and problem-solving activities.</i>
	Presentation of these materials to the patient for discussion.	
	Development of potential solutions.	
Stage 3: Praxis/Action	Implementation of solutions followed by reflection on the effectiveness of actions and, if appropriate, new action steps.	<i>Include the family in the process of action and reflection.</i>
	Primary responsibility in this step rests with patient.	Primary responsibility in this step rests with patient <i>and family</i> .