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Developing a Nicotine Patch Adherence Intervention for HIV-positive Latino Smokers

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Abstract

This paper describes two phases of formative research that were undertaken to develop a smoking cessation treatment module that has the goal of improving adherence with the nicotine patch in HIV-positive Latino smokers. Each research phase (Phase I and II) was conducted independent of the other and used different methods to inform the development of the intervention. Phase I interviewed $n=14$ smokers who had previous experience using the nicotine patch to gain detailed understanding of how, when, and why they used it; their perceived barriers to using it; and their perspective on ways to improve adherence to it. Phase II provided $n=35$ smokers with brief smoking cessation treatment and nicotine patches, then interviewed them in “near real time” over a two month period about their use of the patch during a quit attempt (e.g., perceived barriers and facilitators). Authors of the paper conducted a qualitative analysis of the themes emerging from the interview transcripts across these two phases. Results indicated that consistent use of the nicotine patch was associated with maintaining high motivation for use (i.e., not necessarily motivation to quit, but motivation to continue patch use); linking its use with established daily routines (e.g., with taking other medications, with brushing teeth); and maintaining realistic expectations for patch efficacy (e.g., that users may still experience some level of craving and/or withdrawal). This information will be used to develop and pilot test a brief treatment module that focuses on improving nicotine patch adherence.

Keywords

HIV; AIDS; smoking cessation; nicotine patch; adherence; Latinos

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1. Introduction

Cigarette smoking is more prevalent among HIV-positive persons than in the general population (Gritz, Vidrine, Lasev, Amick, & Arduino, 2004; Pacek, Harrell, & Martins, 2014). As such, HIV-positive smokers are at risk of developing the diseases associated with cigarette smoking and are at greater risk for developing diseases unique to HIV-positive persons. Moreover, fewer HIV-positive persons are dying from AIDS-related illnesses and more are dying from diseases that result from behavioral risk factors, especially cigarette smoking (Novoa, de Olalla, Clos, Orcau, Rodríguez-Sanz, et al., 2008).

Unfortunately, efficacious smoking cessation programs for this population are lacking. Prior research in this area offered some form of behavioral counseling (e.g., tailored behavioral treatment; motivational interviewing; varying lengths of follow-up) with nicotine replacement (Ingersoll, Cropsey, & Heckman, 2007; Gritz, Danysh, Fletcher, Tami-Maury, Fingeret, et al., 2013; Humfleet, Hall, Delucchi, & Dilley, 2013; Lloyd-Richardson, Stanton, Papandonatos, Shadel, Stein, et al., 2009; Moadel, Bernstein, Mermelstein, Arnsten, Dolce, et al., 2013; Stanton, Papandonatos, Shuter, Bicki, Lloyd-Richardson, et al., 2015; Vidrine, Arduino, Lasev, & Gritz, 2006; Vidrine, Marks, Arduino, & Gritz, 2012; Wewers, Neidig, Kihm, 2000). HIV-positive smokers were able to quit with these treatments, but no treatment was found to work especially well over the long term compared to any number of standard control treatments (Moscou-Jackson, Commodore-Mensah, Farley, DiGiacomo, 2014). One consistent finding that emerged from this literature was that close adherence to nicotine patch treatment predicted better treatment outcomes (Gritz et al., 2013; Ingersoll et al., 2007; Lloyd-Richardson et al., 2009; Vidrine et al., 2006, 2012). One potentially fruitful direction for future clinical research with HIV-positive smokers, then, is to improve adherence with the nicotine patch.

Adherence to the nicotine patch generally tends to be very low (Hollands, McDermott, Lindson-Hawley, Vogt, Farley, et al., 2015). Cost, side effects, and beliefs that nicotine replacement is not effective have been cited as reasons for non-adherence (Balmford, Borland, Hammond, & Cummings, 2011). However, simply providing accurate information to smokers about costs, side effects, efficacy, and safety does not improve adherence (Hollands et al., 2015). This finding argues strongly for a more formative approach to research designed to develop an adherence-based intervention for nicotine replacement. Indeed, qualitative research is especially important when adding new components to existing behavioral treatments (Ritchie & Lewis, 2003).

This paper describes the results of two phases of qualitative research that were undertaken to develop a smoking cessation treatment module that specifically improves nicotine patch adherence with HIV-positive smokers.¹ Each research phase was conducted independent of the other and each phase used different methods (retrospective interview in Phase I; prospective treatment study in Phase II) to inform the development of the intervention (i.e., the results of Phase II did not depend on the results of Phase I). We focused specifically on

¹The research methods, results, and discussion are presented with attention to the COREQ (Tong, Sainsbury, & Craig, 2007) checklist for conducting and analyzing qualitative interviews.

Latino smokers due to their higher risk of AIDS-related (Hariri & McKenna, 2007) and non-AIDS-related diseases (Sackoff, Hanna, Pfeiffer, & Torian, 2006) compared to non-Latino smokers. Although studies have found that Latino smokers want to quit smoking (Collins, Kanouse, Gifford, Senterfitt, Schuster, et al., 2001; see also Tesoriero, Gieryic, Carrascal, & Lavigne, 2010), this population has been historically neglected by health care providers for smoking cessation services (Levinson, Pérez-Stable, Espinoza, Flores, & Byers, 2004; cf., Lloyd-Richardson et al., 2009).

2. Materials and methods

2.1 Phase I

The goal of Phase I was to uncover barriers and facilitators of adherence to the patch during a prior quit attempt. We conducted semi-structured individual interviews with HIV-positive smokers who previously tried to quit smoking with the nicotine patch. The procedures, questionnaires, and interview were conducted in participants' preferred language (Spanish or English). The study was approved by the Institutional Review Boards of RAND and Bienestar Human Services, and participants were further protected by a Certificate of Confidentiality granted by the National Institute on Drug Abuse.

2.1.1 Participants—Media advertising at health clinics and social service agencies serving HIV-positive individuals was used to recruit participants. Individuals were also referred by the staff of Bienestar Human Services, Inc.. Bienestar is a non-profit organization serving the HIV-positive Latino community in Southern California. Interested individuals called the study center for more information about the study and to determine eligibility. Participants were eligible if they were at least 18 years of age, Latino, HIV-positive, smoked at least 5 cigarettes per day for at least the last 20 days, and had used the nicotine patch during any past quit attempt.

2.1.2 Interview regarding past use of the nicotine patch—Eligible participants attended an in-person session with one of two bilingual female research assistants (Master's educated) who explained the study, conducted informed consent procedures, and led the interview. The research assistants were trained by a member of the authorship team in conducting interviews with study participants (JST). Neither research assistant had a previous established relationship with any of the participants.

Participants completed a brief questionnaire that assessed demographic, smoking and quitting history variables, including number of cigarettes smoked per day, number of minutes to smoking their first cigarette of the day upon waking (i.e., as an index of nicotine dependence; see Baker, Piper, McCarthy, Bolt, Smith, et al., 2007) and previous quit attempts (Niaura & Shadel, 2003). They then completed a semi-structured interview that focused on their past experiences with using the nicotine patch. Three broad domains were covered in the interview: Challenges they encountered when using the nicotine patch; whether they had trouble remembering to use the patch; and if they had no trouble remembering, what strategies they employed to help them to use the patch. Interviews were audio-recorded and transcribed. Transcripts were not returned to participants for corrections

or supplemental data collection. Individuals were compensated with a \$30 gift card for participating.

2.2 Phase II

The goal of Phase II was to uncover barriers and facilitators of adherence to the patch in “near real time” during a quit attempt. We provided brief behavioral treatment and an 8 week course of nicotine patch treatment for Phase II participants. We followed them for 8 weeks, calling them up to seven times during that period to assess their use of the nicotine patch. The procedures, questionnaires, and interview were conducted in participants preferred language (Spanish or English). The procedures of Phase II were approved by the Institutional Review Boards of RAND and Bienestar, and participants were further protected by a Certificate of Confidentiality from the National Institute on Drug Abuse.

2.2.1 Participants—Participants were recruited using the same procedures as in Phase I. The inclusion/exclusion criteria for Phase II encompassed the criteria for Phase I but additionally included: being motivated to quit smoking, as indicated by a score in excess of 150 on their responses to two questions (each scaled from 0–100, from 0 (not at all) to 100 (extremely): “How motivated are you right now to quit smoking?” and “How confident are you right now to quit smoking?”. This motivation inclusion cut point has been utilized in prior clinical trials with smokers (see Shadel, Martino, Setodji, Cervone, Witkiewitz et al., 2011). Individuals were excluded from participating if they reported being or having been treated for a number of medical and/or psychological conditions within the last 12 months (e.g., heart disease, diabetes, chronic obstructive pulmonary disease, skin allergies or allergies to adhesives; being actively treated for depression) or were receiving treatment for smoking cessation. Women who were pregnant or who were planning to become pregnant in the next 30 days were also excluded. These exclusion criteria were employed because they are contraindicated for the nicotine patch.

2.2.2 Brief treatment and nicotine patch protocol—After completing baseline questions as in Phase I (see above), participants were provided with a 20 minute smoking cessation treatment (see Shadel & Niaura, 2003). The treatment was delivered by one of two bilingual research assistants who was trained and supervised by PhD level psychologists (JST, WGS). The treatment provided information on the benefits of quitting, engaging in coping skill building to manage cravings, using social support, and helping participants prepare for a quit day. They were provided with written cessation materials. Participants were also provided with an 8 week three-step course of treatment with the nicotine patch (four weeks using a 21 mg dose; and two weeks each using the 14 mg and 7 mg dose, respectively) if they smoked 15 cigarettes per day. Participants were given a two-step course of nicotine patch treatment (14 mg for four weeks; 7 mg for four weeks) if they smoked less than 15 cigarettes per day. They were provided with instructions about proper use of the patch and what to expect regarding side effects.

2.2.3 Interview regarding current use of the nicotine patch use—Participants were proactively called by one of two female research assistants (Master’s educated) one to two times per week during the eight week assessment period (trained and supervised as

before by JST). Neither research assistant had a previous established relationship with any of the participants. Each call consisted of a semi-structured interview that assessed three domains: ease or difficulty of using the nicotine patch; whether any physical, psychological, or environmental barrier prevented them from using the patch; and strategies they were enacting to remember to use the patch. Interviews were audio-recorded and transcribed. Transcripts were not returned to participants for corrections or supplemental data collection.

Participants who completed the study were compensated with \$20 for the initial in person session, and then up to \$100 for completing all of the phone interviews.

3. Results

3.1 Phase I

3.1.1 Sample description—The first column of Table 1 provides descriptive information on the Phase I sample ($n=14$; eight were Spanish-speaking).

3.1.2 Interview analysis—Interviews lasted an average of 18.6 minutes ($SD = 4.7$). Interview transcripts were reviewed and the responses to the three domain questions (i.e., what barriers they encountered when using the patch; whether they had trouble remembering to use the patch and what strategies they used to remember) were extracted and coded by one member of the research team (JST) and reviewed and supplemented by a second team member (FHG). Frequency of a particular response out of the total number of responses to a particular question is reported below. Direct quotes for some responses are provided below to enhance these frequency data.

3.1.2.1 Barriers to using the nicotine patch: A total of 13 responses were provided (one by each participant), and they were split between two broad classes of barriers. First, six responses identified *side effects*, in particular skin irritation as a challenge.

“It felt kind of tight. It was uncomfortable....you pull the hair and it leaves a mark.”

“Regardless of where I put it...my skin was still itching through the patch so I’d scratch right on the patch.”

The other seven responses reflected a *belief that the patch was not working* or that it was working too slowly.

“I’d put the patch on, and I was smoking about five or 10 minutes later and I’d get mad and say ‘I’m going to take this thing off. It doesn’t work’. And I threw them in the trash.”

“I felt nothing, absolutely nothing. To me, applying the patch was like applying a Band-Aid.”

“I thought it [the nicotine patch] was going to make magic...just put in the nicotine [but] you still have a little craving there”

3.1.2.2 Trouble remembering to use the nicotine patch and strategies implemented in order to remember to use the patch: None of the participants reported having difficulty

remembering to use the nicotine patch. Three of 11 did not report using any specific strategy to help them to remember to use the patch. One out of 11 participants reported that they kept the patches in sight for easy access. Seven of 11 participants said that they remembered to use the nicotine patch by making its application part of their daily routine.

“...when I was going to brush my teeth I had them in front of me. I knew they were there.”

“I had to take my medicine and when I took my medicine I applied the patch....I have a clock that rings when I have to take my [HIV] medicine. So I knew I also had to apply the patch.”

“I put it where, you know, like the deodorant and the perfumes and the colognes are, which is what I do in some of the medications that I take and they're right here and I'm going to make sure that I put it on. But that's how I remember things.”

3.2 Phase II

3.2.1 Sample description—The second column of Table 1 provides descriptive information on the Phase II sample ($n=35$; 25 were Spanish-speaking).

3.2.2 Interview analysis—A majority of participants (87.5%) in the Phase II study adhered to the instructions to use the patch every day (adherence was defined as using 6 patches per week (Schnoll et al., 2010). Participants completed an average of 86% ($SD = 23\%$) of their scheduled phone calls through the eight week period. Interviews lasted an average of 21 minutes ($SD = 7.7$). Responses to the interview questions were extracted by one member of the research team (FHG) and reviewed and supplemented by a second team member (WGS). Participants typically offered more than one response to each question (i.e., gave multiple answers when asked about strategies used to remember to use the patch). As such, the number of responses for a particular domain almost always exceeds the number of participants. In addition, a majority of participants provided the same responses across each of the calls to the same question (“Nothing has really changed since we last spoke”). As such, only the first response per participant per question was counted in the analysis. Direct quotations from participants’ transcripts are used to enhance the frequency data reported below.

3.2.2.1 Factors that made it easy to use the nicotine patch: A total of 50 factors were identified that made it easy to use the nicotine patch. Twentyseven of the 50 responses (54% of all of the responses) indicated that the patch was simply easy to use (i.e., that the instructions were clear, that the nicotine patch was easily placed and worn, that the nicotine patch is easy to transport).

“I’m happy with the size. It’s not too large. I’m happy that it sticks.”

“Instructions are easy. It’s like putting on a Band-Aid.”

Twenty-two of the 50 responses (44% of all responses) indicated that being motivated to quit smoking makes it easy to use the nicotine patch.

“I want to stop smoking and it makes me more willing to use the patch.”

“...I know it’s helping me out. I haven’t missed a dose because I’m motivated.”

The remaining single response (2% of all responses) appeared in only one participant’s data (the participant commented that the patch was easy to use due to a lack of side effects experienced).

3.2.2.2 Factors that made it difficult to use the nicotine patch: Participants identified 14 factors that made it difficult to use the nicotine patch. The only consistent “difficult factor” response across participants involved side effects. That is, seven of the 14 responses (50% of responses) indicated that side effects made it challenging to use the patch.

“...not having any more side effects makes it easier [to use].”

“It’s been somewhat easy to use the patch today because I haven’t experienced any more side effects.”

The remaining responses for factors that made it difficult to use the patch were unique to specific participants and did not appear with consistency across individuals.

3.2.2.3 Physical, psychological, and environmental factors related to nicotine patch use:

Few participants thought that any *physical factor* was related to their use of the nicotine patch. Only 5 responses were generated, and all of these responses indicated that improved physical performance or activity positively influenced their use of the nicotine patch (e.g., “I think it’s making me feel better....I want to use the patch because I know I’m feeling better.”).

Of the 12 *psychological factors* generated, seven were identified as making patch use easier by promoting feelings of encouragement that, in turn, made them want to continue to use the patch (e.g., “I’m happy I’ve been able to quit. This works for me. That’s why I continue to use the patches.”).

The remaining five psychological factors were viewed as making patch use more difficult. These factors primarily involved feelings of stress and negative affect (e.g., “When I feel aggravated, it’s harder to keep the patch on.”).

Five *environmental factors* were identified as making it easier to use the patch, but there was no thematic consistency to the responses across participants.

Nine environmental factors were identified as making it more difficult to use the patch. Eight of the nine were environmental stressors (e.g., “I’m currently couch surfing...I try to keep the box of patches in my suitcase but sometimes I forget.”).

3.2.2.4 Strategies enacted to remember to use the patch: Participants generated a total of 58 responses that they used to remember to use the patch as instructed. A majority (37 of 58 responses or 64%) of these responses involved participants linking patch use to an existing, established daily activity.

“It’s a routine. I put it on after I shower in the morning and put the patches next to my medication.”

“I’ve been putting it on at 8 am every day. I take my medicine at 6 or 7 am and that serves as a reminder that I need to put on the patch.”

“I leave it [the patches] next to my medication and remember to take it at the same time each day.”

The majority the remaining responses (15 of 58 responses or 26%) involved participants placing the patches in an easy to see location.

“I put it [the patches] next to my bed and that helped me remember.”

“I put the box next to my alarm clock in my room.”

“I keep it [the patches] visible so when I see it I remember that I need to put it on.”

The final six responses were unique to individual participants and did not occur with consistent frequency (e.g., asking another person to remind them to use the nicotine patch).

4. Discussion

The purpose of these two studies was to conduct formative research to inform the development of a treatment module that could be used to improve adherence with the nicotine patch in HIV-positive Latino smokers. A short term goal of this research was to develop and add an adherence module to an existing smoking cessation treatment (see Shadel & Niaura, 2003) and then downstream, evaluate that adherence enhanced treatment to determine whether it 1) has an impact on nicotine patch adherence, and 2) whether it enhances smoking cessation outcomes. This research program was undertaken in order to improve smoking cessation outcomes in HIV-positive persons. Clinical research has addressed smoking in this population but no specific treatment has been found to work particularly well over the long term (Moscou-Jackson et al., 2014). Adherence to nicotine patch treatment has been found to be an important component of treatment success with HIV-positive smokers so treatments designed to improve patch adherence may improve cessation outcomes.

Across the two formative research studies, several themes emerged that were associated with nicotine patch adherence. First, participants expressed a belief that the nicotine patch was not working properly or that it was not working quickly enough. Relatedly, some also expressed frustration with their experience of side effects, expecting them to resolve more quickly. With regard to patch efficacy, the nicotine patch only replaces a portion of the nicotine that smokers typically receive through cigarette smoking (Johnstone Brown, Saunders, Roberts, Drury, et al., 2004); as such, participants’ perceptions of efficacy in the current study are very likely accurate. It is possible that higher dose nicotine replacement therapy would help with this issue (Fiore, Jaen, Baker, Bailey, & Benowitz et al., 2008). However, given that use of the nicotine patch may be cost prohibitive (Hollands et al., 2015), another approach may be to educate smokers about the pharmacodynamics of nicotine replacement, amount of nicotine replaced compared to their regularly smoked cigarettes, and what they might expect during the course of their treatment with regard to efficacy.

With regard to side effects, many participants recalled that the experience of negative side effects made it difficult to continue using the nicotine patch. In general, side effects of using the nicotine patch (e.g., skin irritation at the site of local application; sleeplessness) are mild and short lived, but can be a reason for non-adherence (Hollands et al., 2015). But clearly, in this population of HIV-positive smokers, side effects were a concern and prohibited effective patch use during a prior quit attempt. Alternatively, a lessening of side effects made it easier for participants to use the patch properly. In either case, educating HIV-positive smokers about side effects that are associated with nicotine patch use and their typical time course may be an important component of an adherence intervention module.

Second, motivation was cited as a key issue to improving patch use as was the ease with which the patch could be used. Motivation to quit smoking was seen as important to prompting improved adherence and improved adherence was seen as encouraging motivation. Developing an element of treatment that focuses on improving motivation to use the patch may be important in this regard.

Finally, keeping the nicotine patches visible in one's living environment and integrating patch use into an established daily routine were viewed as critical to improving adherence. Participants reported linking patch use to their use of HIV medications, to specific times of the day, and to daily personal hygiene routines (e.g., teeth brushing). This represents an important behavioral strategy that may be particularly salient to HIV-positive smokers. Participants in our studies reported being HIV-positive for about 15 years; in principle, HAART would have been available for most participants upon learning of their diagnosis. Interventions for improving HAART adherence are an important addition to clinical HIV care (e.g., Kalichman, Cherry, Kalichman, Amaral, White, et al., 2013). Thus, linking nicotine patch use to HIV medication routines or other daily activities may be a particularly valuable tool toward improving adherence with the patch.

Two striking (and surprising) features of these results were that none of the strategies participants used to improve adherence with the patch had much to do with being HIV-positive or with identifying as Latino. Based on reviews of this literature suggesting that treatment tailoring might be important for improving smoking cessation outcomes (Moscou-Jackson et al., 2014), we had expected that some cultural tailoring or tailoring due to HIV-status would be important. However, beyond some participants indicating that it was useful for them to link patch use to taking their HIV-medications, a more general strategy - linking patch use with some established daily routine - seemed to be most germane (i.e., most participants who indicated a link to HIV medications also mentioned linking to other daily routines). Issues related to cultural identity or Latino ethnicity were never mentioned. As such, the results on improving adherence with the patch may have implications beyond the population of interest in this study.

Many of the strategies we identified in this research have been used - with varying degrees of success - to improve adherence to medications more generally (e.g., McDonald, Garg, & Haynes, 2002). However, as a cluster of strategies, only one (i.e., general education about side effects) is a part of routine nicotine patch education; the other strategies (i.e., education about expected nicotine patch response, improving motivation to use the patch, and linking

patch use to daily routines) have not been applied specifically to improving nicotine patch adherence. Thus the findings reported in this paper are novel for the smoking literature. In addition, the strategies generated by participants were broadly consistent with contemporary theories of medication adherence (e.g., DiMatteo, Haskard-Zolnierrek, & Martin, 2012) which have postulated that providing accurate information, improving motivation, and helping people overcome practical barriers to medication administration are important for improving adherence. The present research was undertaken in a largely atheoretical fashion in order to allow patient experiences to shape the strategies that could be used. Nonetheless, it is important to note how similar patient experiences were with extant theories and this convergence should help to frame future research in this domain of inquiry.

Limitations to this research need to be noted. First, the samples for the studies were drawn from the Latino community in Los Angeles, and may not be representative of populations in other cities. Second, the Phase I and Phase II samples differed from one another, likely due to differences in the motivation to quit composition of the samples. Finally, this study focused specifically on improving adherence to nicotine patch; as such, it is not known if any of these findings would apply to improving adherence with other smoking cessation medications or treatments. In any case, these data could serve as the foundation for a module that could be added to other smoking cessation treatments (Fiore et al., 2008) and evaluate whether it improves adherence and cessation in HIV-positive smokers or smokers in general.

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Highlights

- The results of two formative qualitative studies suggest that improved adherence with the nicotine patch for HIV-positive Latino smokers include information around:
 - Safety and side effects of the nicotine patch
 - Realistic expectations for nicotine patch efficacy
 - Problem solving to weave patch use into daily routines, including HIV medication schedules
- These adherence strategies may have implications beyond HIV-positive and Latino smokers.
- Research is needed to evaluate whether including such an adherence intervention to smoking cessation treatment improves clinical outcomes.

Table 1

Participant characteristics for each study phase.

Variable	Phase I (<i>n</i> = 14)	Phase II (<i>n</i> = 35)
Mean age (<i>SD</i>)	46.0 (8.9)	47.3 (7.4)
Gender (% male)	82	70
Education		
% less than high school	64	33
% high school graduate or GED	9	34
% greater than high school	27	33
Mean years HIV-positive (<i>SD</i>)	14.7 (9.7)	16.3 (8.7)
Mean cigarettes smoked per day (<i>SD</i>)	11.4 (6.0)	13.0 (7.0)
% Smoke within 30 minutes of waking	55	49
Mean number of past year quit attempts (<i>SD</i>)	5.4 (7.7)	1.9 (1.3)
Mean longest days quit in past year (<i>SD</i>)	12.6 (19.3)	20.4 (58.9)