






Implementation of HIV Prevention Interventions with People Living with HIV/AIDS in Clinical Settings: Challenges and Lessons Learned

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Abstract Integrating HIV prevention into the clinical care flow that since every new HIV infection begins with of people living with HIV has emerged as a priority in the an infected person, HIV prevention efforts must focus on US As part of a cross-site evaluation this study examined PLH/A (CDC, 2001). While the concept of promoting HIV the processes by which 15 clinic-based projects implemented prevention among patients living with HIV in clinical mented interventions funded under the Health Resources and Services Administration's (HRSA) HIV Prevention with Positives (PwP) in Clinical Settings Initiative. We closer inspection. Our objective in this article is to begin to conducted 61 in-depth interviews with researchers and interventionists across the 15 projects. Intervention implementation was feasible assuming several key components were in place: (1) internal leadership to overcome resistance and foster interest and motivation among clinical providers and staff; (2) adequate attention to creating seamless integration between clinic practice and intervention; and (3) ongoing training that met clinician and staff needs as prevention interventions become a regular part of care. Interventions well matched to the clinical environment and the patient populations were feasible and acceptable to health care providers, prevention interventionists, and clinic staff.

Keywords HIV prevention with positives Intervention implementation Qualitative process evaluation

Introduction

In the US, the shifting landscape of HIV prevention includes behavioral interventions designed to reach people living with HIV/AIDS (PLH/A) in healthcare settings.

Our qualitative evaluation examined the processes by which 15 demonstration sites, funded under the Health Resources and Services Administration's (HRSA) Special Projects of National Significance (SPNS) Initiative on Prevention with HIV Infected Persons Seen in Primary Care Settings, sought to address the issues uniquely related to the integration of HIV prevention and care in order to implement clinic-based HIV prevention interventions. We present findings from the first phase of an on-going process evaluation specifically focused on the opportunities and challenges associated with intervention implementation among the demonstration projects.

Evaluating HRSA Demonstration Projects

In September 2003, HRSA funded 15 demonstration sites and an evaluation center under the SPNS HIV Prevention with Positives (PwP) in Clinical Settings Initiative. The purposes of the PwP Initiative were to test whether

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behavioral interventions in medical care settings helped the planning and goals of the intervention; the particular people living with HIV reduce their risk of transmitting challenges of designing and developing the interventions; HIV and to identify appropriate intervention models for training of interventionists; and clinic and patient population-specific patient populations and care settings. Research issues that affected the development, implementation and integration of the intervention. All interviews were audio-recorded and transcribed verbatim.

Provider (e.g., MDs, NPs, PAs) or Specialist (e.g., health educators, social workers) delivered model. See Malitz et al. (2007) in this issue for a description of the history of the SPNS Initiative.

The Enhancing Prevention with Positives Evaluation Center (EPPEC) at the University of California, San Francisco designed a comprehensive evaluation of the contrast to basic or theoretical research, social policy demonstration projects. The EPPEC quantitative evaluation research responds to specific information needs which can measure the outcomes of the interventions over time when they can be translated into action. The benefit of this type of analysis is that the stages of analysis are transparent and the objectives of the qualitative analysis follow a well-defined procedure of sifting, charting, and evaluation are to understand how and why the outcomes of the interventions are produced (Patterson, 1992). The specific aims of this on-going qualitative evaluation are to: (1) provide context for better understanding of the outcomes of the interventions across clinics, and (2) assess feasibility and acceptability of implementation process for replication of successful interventions. The study design includes in-depth interviews and a review of secondary data, e.g., intervention manuals over three phases: pre-implementation, implementation, and post-implementation. This article presents findings based on pre-implementation data collected as part of a larger prospective evaluation study.

Methods

Pre-implementation Phase Sample and Recruitment

We conducted in-depth interviews with 15 PIs, 1 co-PI, 15 project directors, and 30 interventionists (n = 61). Our sample of interventionists was self-evident in five clinics because they were the sole hire on the project. In clinics with more than two interventionists, we asked the project director to assist us in purposively selecting whom to interview. Our sampling criteria were that they had already undergone training, but not yet begun implementing the intervention.

Interview Process and Guides

All participants were interviewed between April and December 2004. Interviews typically took place in a private space within the clinic or nearby. In-depth interviews were conducted by one of the first three authors using a semi-structured interview guide. Interviews lasted from 40–60 min. Participants were asked questions pertaining to

Our analytic approach followed a process called Framework Analysis (Ritchie & Spencer, 1994). This type of analysis originated in the context of applied social policy research. In

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After importing the transcribed interviews into Atlas.ti, software developed to facilitate the organization and management of qualitative datasets, we familiarized ourselves with a subset of the data. The analysis team individually read seven interviews, making note of their observations and potential codes to share during team meetings in the early stages of codebook development. We re-read the subset of interviews, meeting bi-weekly for 6 weeks to discuss observations and to refine our codebook. With the establishment of the codebook, each interview was coded by a primary analyst and verified by a secondary analyst.

The first author read all coded interviews to check for consistency in the application of the codes. Segments associated with a particular code of interest were synthesized into a summary and visually displayed in a chart to facilitate the comparative similarities and differences across interviews and intervention models.

As noted earlier, HRSA recommended using either a Provider or a Specialist-delivered intervention model in their call for applications. While the majority of researchers followed these recommendations and selected either a provider or a specialist model, a minority designed interventions that included peers, or created a model using both providers and specialists or a combination of providers, specialists and peers. Table 1 illustrates the characteristics

Table 1 Site characteristics

| Intervention model | Patient eligibility | Theory and/or models adapted | Brief description of intervention components |
|---|--|--|---|
| <i>Provider-delivered</i> | | | |
| Johns Hopkins University, Baltimore | All patients eligible, including new and returning patients | Transtheoretical Model of Behavioral Change (TTM) (Prochaska, DiClemente, & Norcross, 1992) | Computerized behavioral risk assessment generates stage-based profile for provider. Brief counseling by primary care provider during routine medical visit |
| University of Alabama, Birmingham | Male patients reporting sexual activity with other males in last 6 months | TTM (Prochaska & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992) | Computerized behavioral risk assessment generates stage of change-based brief message and prescription printed for primary care provider delivery during routine clinic visit. |
| UC Davis | Patients with sex or drug risk ^a in last 6 months | TTM (Prochaska & DiClemente, 1982; Prochaska, DiClemente, & Norcross, 2005) Motivational interviewing (Miller & Rollnick 1991) | Self-administered written risk assessment info is used by primary care provider to conduct brief stage-based counseling using elements of motivational interviewing during routine clinic visit |
| County of Los Angeles | All returning patients reporting sexual activity ^b in last 3 months | Partnership for Health (Richardson et al., 2004) | Provider administers sexual health risk assessment to determine brief HIV prevention loss-frame messages and a behavioral prescription delivered by primary care during routine clinic visit |
| <i>Specialist-delivered</i> | | | |
| St. Luke's Roosevelt Hospital, New York | All returning patients | Motivational interviewing (Miller & Rollnick, 1991) TTM (Prochaska & DiClemente, 1984) | Social worker administers brief risk assessment during first session, four motivational interviewing sessions in total which may or may not coincide with primary care visits and are in addition to routine case management |
| University of Washington Seattle | All patients | Motivational interviewing (Miller & Rollnick, 1991) TTM (Prochaska, DiClemente, & Norcross, 1992) Harm Reduction | Intervention group received minimum of four counseling sessions with Specialist using motivational interviewing and six peer support group sessions |
| El Rio Health Center Tucson | All patients | Social Cognitive Theory (Bandura, 1994) Adaptation: Healthy Relationships (Kalichman et al., 2001) | Group views film clips to initiate discussion on relevant topics such as stress and HIV, disclosure, relationships and safer sex/risk reduction. Five sessions, 120 min each, over 5 weeks. |
| <i>Provider + Specialist-delivered (Mixed)</i> | | | |
| DeKalb County, GA Health Educators | Patients reporting sexual activity ^b or drug use in the last 3 months | TTM (Prochaska, DiClemente, & Norcross, 1992) | PCP gives brief prevention message every 6 months. Targeted risk behaviors are assessed by the health specialist and tailored stage-based counseling is provided in conjunction with regularly scheduled primary care visits every 3 months |
| Whitman Walker Clinic, Washington, DC Health Educator | Male patients | TTM (Prochaska, DiClemente, & Norcross, 1992) | PCP provides brief risk reduction message. Specialist conducts risk assessment and tailored stage-based counseling during 3, 30 min counseling sessions within 45 days of baseline |
| Drexel University Philadelphia Health Educator | Female patients | Gender and Power Theory (Wingood & DiClemente, 2000) AIDS Risk Reduction Model (Catania, Kegeles, & Coates, 1990) | PCP determines risk and stage of change based on a personalized discussion of risk and delivers a stage-based prevention message. Intervention group receives additional facilitated Specialist led group sessions and two peer led support sessions. |

Table 1 continued

| Intervention model | Patient eligibility | Theory and/or models adapted | Brief description of intervention components |
|---|---|---|--|
| University of North Carolina, Chapel Hill Social worker | Patients reporting sexual activity or IDU in last 6 months [§] | Motivational interviewing (Miller & Rollnick, 1991) | PCP delivers a brief prevention message based on a computerized risk assessment during regularly scheduled primary care visits. Intervention group receives in addition: 3–40-min motivational interviewing sessions w/ social worker over 3 months |
| Owen Clinic, UC San Diego Health Educator | Patients reporting risk in last 6 months [§] | TTM (Prochaska & DiClemente, 1983) Motivational interviewing (Miller & Rollnick, 1991) Harm Reduction | Intervention group received brief loss frame message from provider based on computerized risk assessment during primary care visits. Intervention group receives additional stage of change assessment and targeted counseling with health educator in 4 one hour sessions |
| <i>Peer-delivered</i> | | | |
| Fenway Community Health Boston | All MSM patients | IMB theory (Fisher & Fisher, 1993) TTM (Prochaska & DiClemente, 1984) Motivational interviewing (Miller & Rollnick, 1991) | Nine sessions (intake, four module sessions, four booster sessions) based on computerized modular workbook guided by peer interventionist. Client chooses modules. Sessions last 50 min |
| Mt. Sinai Hospital, Chicago | Patients diagnosed with HIV for at least 3 months | TAP adaptation (McKirnan et al, 2001) | Four educational sessions focusing on medication adherence, safer sex practices, mood management, communication skills, alcohol/drug use over six months. |
| University of Miami | Patients over age of 45 reporting unprotected sex in last 12 months | IMB theory (Fisher & Fisher, 1993) Adaptation: NIMH HIV Prevention Trial (1999) | Group sessions facilitated by a peer focusing on building skills and increasing knowledge and motivation 4 sessions in total, two sessions a week. |

^a Risk defined as shared injection equipment, practiced unprotected sex with + or unknown partner, or someone other than a regular sex partner

^b Sexually active defined as oral, vaginal or anal sex

^c Sexual activity or risk is not defined

of each of the 15 sites including type of intervention, intervention theory or adaptation, intervention description, eligibility criteria, and type of risk assessment. For the sake of comparison, we briefly lay out the four main intervention models below, followed by an in-depth description of the implementation issues associated with each.

1. Provider-Delivered PwP Interventions ($n = 4$)

The patient's primary care provider (PCP) delivered the intervention during routine HIV care visits. Patients' risk of provider- and specialist-delivered, while one site designed a provider-delivered, specialist-delivered, or peer-delivered intervention. For the purposes of manageability, we assigned this latter intervention to the provider + specialist category. provider delivered a brief prevention message tailored to the patient.

2. Specialist-Delivered Interventions ($n = 3$)

Specialist interventions occurred either in conjunction with or apart from routine clinical visits and took place over four to five counseling sessions in individual or group settings. Counseling topics included safer sex, medication use, relationships, disclosure, emotional well-being, assertiveness training, and other patient-defined priorities.

3. Specialist + Provider-Delivered Interventions ($n = 5$)

A hybrid of the above models, the providers used brief stage-based or prescribed prevention messages based on patient risk assessment delivered during a routine visit. In addition, the patient attended three to five counseling sessions with a health educator or social worker covering content areas similar to those described under the Specialist

intervention. Of the fifteen sites, four were a combination of provider- and specialist-delivered, while one site designed a provider-delivered, specialist-delivered, or peer-delivered intervention. For the purposes of manageability, we assigned this latter intervention to the provider + specialist category.

4. Peer-Delivered Interventions ($n = 3$)

Similar to the specialist intervention, the peer interventions occurred in conjunction with or apart from routine

Provider-Delivered Interventions

Intervention Description and Rationale

Interventionists in these four locations were HIV PCPs, and predominantly infectious disease physicians. With one exception, the PIs of these interventions were themselves HIV-negative casual partners of HIV PCPs. This was important for several reasons. First, at least one provider, the PI, was convinced of the importance of providing HIV prevention on a routine basis during a clinic encounter. Second, as a PCP working within the clinic, they had some power to affect the clinical practices of other providers, including persuading the medical director to endorse and enforce the changes necessary to implement the intervention. Finally, they were not perceived as outsiders by the other providers, and were able to leverage these collegial relationships when necessary to gain acceptance of the PwP intervention from reluctant clinicians.

Interviewees among these sites perceived that integrating HIV prevention and care would continue to increase in popularity, and they believed themselves to be leaders in clinic-based HIV prevention. They were aware and clearly supportive of the national PwP trend (due to conferences, new federal guidelines, and increased interest within the medical establishment) to provide prevention services to people living with HIV/AIDS. Thus, PIs recognized the need for PCPs to become proactive in the area of HIV prevention and selected a provider- rather than specialist- or peer-delivered intervention. Further, PIs described three underlying reasons to explain their choice of intervention model. First, PCP interventions are effective because of the persuasive power of the physician to facilitate patient behavior change. Second, PCP interventions are effective because patient—patient-physician contact is virtually guaranteed whereas a specialist required an additional appointment. Finally, perhaps the most important rationale is that they believed the time had come for PCPs to be involved in HIV prevention.

Prevention Concept, Intervention Content and Tools: Provider Interventions

Integrating HIV prevention counseling into a 20–30-min routine patient visit demanded brevity. The content of the prevention counseling or prevention messages depended on the theoretical basis of the intervention and the information reported by the patient on the risk assessment.

All four interventions assessed patient risk just prior to the routine clinic encounter or in a face-to-face discussion with their clinician. Aided with specific risk information such as sexual activity, condom use, number of sexual partners, and use of illicit drugs, PCPs were able to provide tailored recommendations to patients or embark on a discussion with patients about risk taking. For example, in one site, clinicians relied on a printed cue sheet included in the patient chart containing a tailored and scripted prevention message, e.g., a patient reporting having had receptive anal sex without a condom with an HIV-negative casual partner was advised to think about increased his chances of catching an STD. In another site, a PCP who having unprotected, receptive anal intercourse increased his chances of catching an STD. In another site, clinicians were trained in motivational interviewing (Miller & Rollnick, 1991) and were expected to help patients identify risk and facilitate goal setting around risk reduction following the tenets of harm reduction, which focus on small incremental steps toward behavior change. The PI described the applicability of motivational interviewing below:

It's the technique; you don't have to know anything about the topic that you're working with really. 'Cause all you're doing is probing your patient's mind and getting them to come up with their own answers. It's gonna be far more powerful if they come up with it themselves. That's why we chose motivational interviewing, not didactic, not the proscriptive, even though our prescription says we've agreed to work on the following things before our next visit. And it has a list of high-risk activities that the patient is gonna choose one that they want to work on because they feel a sense of responsibility. PI

Three of the 4 provider-delivered interventions were based on the Transtheoretical Model of Behavior Change Theory (Prochaska & DiClemente, 1984). They included an assessment of the patients' stage of change for key risk behaviors, a tool to convey this information to providers, and training that instructed PCPs on how to best impart stage-based counseling messages. These interventions appealed to PCPs because they allowed them to deliver a very specific and tailored behavioral message, without requiring a lengthy counseling process. It also closely mirrored their familiar clinical paradigm, in that they were able to "diagnose" a behavior by isolating a specific risk, stage that risk in terms of willingness to change, and then deliver the corresponding "prescription"—the stage-

specific prevention message.

Implementation Challenges Encountered

Sites faced distinct challenges associated with implementing provider-delivered interventions. Project staff needed to make HIV prevention a clinical priority, cope with PCP skepticism regarding time constraints and clinic information such as sexual activity, condom use, number of sexual partners, and address the need for training and skill-building in risk assessment and behavioral counseling. PIs, because of

their “insider knowledge” as clinicians, understood these challenges: *Implementation Resolution: HIV Prevention Becomes Relevant*

The practicing physician is always pressed for time. Even with a half an hour appointment. These folks are so complex and require so many referrals and so on, that a half an hour is often not enough time. And now we’re gonna add 5 min to it. And I think that’s a big psychological barrier for a doc. PI

Meanwhile, some PCPs anticipated feelings of discomfort associated with changing the way they approached the topic of HIV prevention:

The whole issue of trying to change how you talk to patients is a little awkward. I’ve known these people, I mean, some of them for many, many years. And I have my own way of talking to them about these issues. So, I’m not sure yet what’s gonna happen if I try to change the way I speak to patients to fit these models. But, I’ve elected to give it a try. Provider

PIs raised awareness of the importance of clinic-based HIV prevention by presenting their colleagues with compelling local and national epidemiological studies illustrating the rise in STD cases. Two sites conducted formative research to identify the extent to which prevention was already occurring and the extent to which PCPs felt it was their responsibility to conduct prevention. Armed with this essential formative data, PIs proceeded to develop an intervention that resonated with their PCPs and addressed their concerns in an informed way. In a couple of sites, researchers solicited input on intervention design from the PCPs so they were included in the process and felt some allegiance to the intervention. Overall, PIs and their staff worked on the logistical preparations to understand the flow, context and culture of the clinic in order to make the intervention seem complementary rather than controversial and obtrusive to other clinic services and procedures. A PCP interviewee described the positive results produced from these careful preparations:

I think that the only way that this intervention worked was that the PI just had this dogged determination to keep us all on top of it. But the fact that the PI drilled it into us and gave us all kinds of reminders, you must protect this day, and got the division to buy into it and the clinic to buy into it and how we schedule things that day. And that seems like a minor point but if the scheduling didn’t work then the whole thing was shot from the beginning.... They had it arranged so that people who were on call, somebody else covered their beeper. Because it’s the only way it could get done. Provider

We observed a pattern among providers indicating that the formal and informal support among providers contributed to building momentum to conduct HIV prevention in the clinical encounter. PCPs’ first-hand experience and frustration with patients returning with STDs fostered support for HIV prevention in the clinical environment. Many lacked training and experience with behavioral counseling, but once trained, they expressed optimism that incorporating HIV prevention into the medical visit was feasible:

I think my comfort level in discussing the details of a patient’s personal life as far as the sexual life I think need to be better. So just bringing up these things and finding out that every once in a while I’ll kind of stammer and not let the words just flow out as they should when I ask these questions, I think it’s more in the interest of hey I’ve got to get better at this (but) I have to become more knowledgeable in this area. Provider

Once trained in behavioral counseling and in intervention delivery, PCPs perceived the value in providing specific and tailored prevention messages as they believed they were more effective in generating behavior change than generic messages they had been accustomed to delivering:

I think it helps to have the idea of the transtheoretical model of change behind it, because [now] I’m kind of shotgunning a couple of different risk factors. I just kind of say, “don’t do that. Be good”.... it’s the targeting to the individual I think that’s going to help get the message across better than the kind of bulky “be a good person” kind of message that I’m sending which isn’t so specific. Provider

Specialist-Delivered Interventions

Intervention Description and Rationale

The three sites employing specialist-delivered interventions worked with health educators or social workers. Each site described an expansive concept of what HIV prevention entailed. Rather than brief targeted behavioral messages, they designed a broad curriculum and an open format that allowed the patient to identify issues for discussion. Research staff explained they designed interventions intended to enhance the capacity of pre-existing “specialists,” e.g., case managers and social workers, whose role was to support patients in negotiating between physician directives and the social issues they faced day to

day. This intervention model would be difficult for physicians to provide within the time-constrained context of a primary care visit because they were specifically designed to encourage lengthy in-depth engagements between patient and specialist.

Sites that chose specialist-delivered interventions had some HIV prevention activities in place prior to this intervention. One of the clinics had already implemented an annual risk assessment and offered HIV testing services to sex partners. However, the two other sites were not exceptional in their HIV prevention efforts prior to the intervention. Although individual providers and medical directors endorsed HIV prevention, the clinics did not have written procedures, practices or guidelines in place at the organizational level.

Prevention Concept, Intervention Content and Tools: Specialist Interventions

The specialist sites were united on two key concepts: (1) the prevention intervention must address a range of social, economic, and psychological issues, and (2) the patient must actively engage in the intervention process, rather than passively receiving education or messages. The central issues to be addressed included stigma, disclosure, loneliness, self-isolation, personal responsibility and quality of life—all of which require intensive and interactive interventions. One site described its intervention goals as “health maintenance, healthy sexuality, happiness, and well being.”

These interventions differ from the “scripted” provider-delivered messages; patients and specialist worked together to identify factors that patients perceived put them at risk, to understand patients’ motivation to engage in risky behaviors, and to identify strategies patients could use to successfully change those behaviors. They used a variety of frameworks including Motivational Interviewing, the Transtheoretical Model, and the Social Cognitive Model (Bandura, 1994). Some had one-on-one counseling; others used discussion groups (see Table 1). Most of the interventions included risk assessments that were computerized on paper, or administered by the specialist, and some followed a curriculum outlining the content for each session. Yet beyond the predefined categories of risk on the assessment, patients worked with the specialist to identify and address other behaviors or issues the patients deemed relevant or problematic in terms of HIV transmission. All three sites discussed the importance of patient engagement, defining the process as a dynamic exchange between patient and specialist:

In health belief models and in medical management of disease or social problems, things are seen quite

linearly, and that the change is progressive (which it isn’t always). And the doctor is the expert and that information is known and delivered, and then the patient digests it and then somehow changes. And there has been a whole lot of research that shows that that is not the case, and it’s just the shutdown of two parties in the interaction. So the whole technique of doing MI really shifts the power dynamic. It takes more time to do certainly. This is the biggest criticism. It takes longer to get a sense of what people’s beliefs and feelings are than to give a tier. Specialist

Implementation Challenges and Resolutions

Implementation challenges associated with specialist-delivered interventions were minimal. Researchers directed their energies toward creating or modifying behavioral counseling interventions for their clinical settings and securing appropriate training for the specialists. Because most existing counseling interventions were designed to be with a mental health focus, the protocols and trainings were not as difficult to locate and adapt as the provider-delivered interventions. In general, the PIs and project directors in these sites did not have to undertake extensive efforts to develop buy-in from the providers or clinic staff. Perhaps because the specialists in all three clinics were counselors or educators by training and profession, they did not need to be convinced of the need, importance or validity of behavioral interventions. Clinical providers were not asked to take on any additional responsibilities or demands on their clinic time other than referring patients to the intervention services.

Recruitment and retention of patients were anticipated as the major concerns of the specialist interventions. All of the interventions were multi-session models with sessions designed to last a minimum of 30 min. Two of the three interventions required clients to return for independent counseling sessions, separate from their medical appointment. The third clinic intended to coordinate all the intervention sessions with the patients’ medical visits. PIs, project directors and specialists expressed concern that some patients, particularly high-risk patients, would be unwilling to participate or have difficulty returning for the intervention sessions. They cited a variety of social barriers, such as substance abuse, marginal housing, lack of transportation and chaotic life circumstances. Sites proactively strategized to address some of these potential barriers. The interventionists and project directors believed that the powerful nature of the intervention in terms of meeting patients’ needs would best facilitate retention. They all discussed the importance of “connecting” or establishing rapport with patients during the first session. And finally,

they attended to practical issues such as providing transportation, placing reminder telephone calls in advance of sessions, and making an effort to discuss issues that prevented patients from coming in. However, project staff realistically expected that patients would continue to have competing priorities as indicated by the high rate of no-shows to routine clinic appointments.

Provider + Specialist-Delivered Interventions

Intervention Description and Rationale

Five of the fifteen sites designed mixed or hybrid interventions which combine the intervention efforts of PCP and specialists. PIs took seriously the CDC guidelines outlined in *Advancing HIV Prevention: New Strategies for a Changing Epidemic* (2001) to incorporate HIV prevention counseling as standard of care. However, they explained that patients' needs would likely outstrip the resources of the providers therefore they added a specialist intervention component. In three of the five clinics, PIs expressed skepticism that providers would be effective in changing patient behavior, or that PCP would take the time to carry out the new standard of care:

Since we have a history of having health educators at our clinic, we thought that the mixed model would probably be a good choice for us. From the beginning, we felt that there would be a lot of challenges if we just relied solely on our providers to provide the messages, and we felt that we needed something in addition to our providers to back that up. And to go with just the specialist model, I know that, that there are some sites that are just doing like social workers or something like that. We felt that that just wasn't really the purpose of the RFA and it kind of would be just another excuse for our providers not to be providing the messages, and we just felt that it was really important that our medical providers, and that everyone at our clinic start talking about prevention. PI

In one location, a mixed intervention design resulted from physicians identifying both a need to effectively address HIV prevention, because of the increasing number of patients presenting with STDs, as well as a need for additional support services within the clinic. Overall, there was consensus across sites that certain patients would require additional services that PCPs simply could not provide because patients needed and "deserved" more intensive or tailored interventions:

I was really interested [in] trying to design an intervention that got at some of the underlying issues instead of just walking into a room and telling people to

use condoms, to try to deal with the reality that condoms may not be safe for some people that, you know, there's violence or all these other issues that women are dealing with, and lot of it has to do with just their social reality and what's going on culturally and socially. Specialist and Intervention Developer

The mixed sites were similar to other clinics in terms of pre-intervention prevention activities which were carried out on a case-by-case basis. Two of the five sites had formal risk assessments that every new patient was required to undergo, but only one of the five formally re-evaluated risks. In some sites, prevention discussions were happening at the discretion of the providers, e.g., during family planning discussions, presence of an STD, or when a patient brought it up. Providers working in a setting that served women only were having prevention discussions on a routine basis, because STD risk and family planning discussions were normative for both patients and providers during gynecological exams. In contrast, two clinics focused exclusively on HIV treatment. The following quote illustrates the biomedical focus of the clinicians:

The Clinic didn't have a formal intervention program prior to this. You know, condoms were available, educational materials are in the waiting room, but there's nothing on paper, pulled together. So this is the first opportunity to put prevention into a clinical setting. They provide magnificent treatment and care, but there's nothing warm and fuzzy about it. You go in there and you're getting the best care. And that's what they're there to do, and that's what they do really well. There's no support groups. There's nothing for the individual to meet their other than clinical needs. PI

Prevention Concept, Intervention Content and Tools: Provider + Specialist Interventions

The single unifying theme among the mixed sites on the concept of HIV prevention was that patients would most benefit from a two-prong intervention that included a message delivered by a provider followed by a lengthier visit with a specialist. Both components followed the structure of risk assessment followed by prevention messaging or counseling of the provider- or specialist-delivered interventions. The specialist components were diverse in content and form, but consisted overall of discussions based on either a formalized curriculum, a broader patient-directed counseling session with a health educator, or, in one case, a social worker—again, much like the specialist-only interventions.

Overall, these interventions were not always conceptualized as collaborations among provider, specialist and patient. There were few formal tools created to coordinate the counseling received by patients in the mixed interventions. Communication between the specialists and providers, when it occurred, was typically informal. The intent and structure of these interventions was not necessarily designed to improve the relationship and interaction between specialist and provider staff.

Implementation Challenges Encountered

Incumbent upon those implementing a mixed model was attending to a diverse set of actors, e.g., clinic staff, PCP and specialists. With that came the real possibility for criticisms and resistance that could potentially dilute the power and scope of the interventions. Some clinics were more prepared and willing to make the significant changes required of them—working to smooth patient flow, changing the standard of care procedures, facilitating the enrollment of patients into the specialist intervention—than others. The challenges we lay out below were resolved to varying degrees among the five sites and were highly dependent on the support of clinic leadership as well as a willingness on the part of clinic staff to cope with the added burden of running an intervention demonstration project in a busy clinical setting.

Dually burdened: Notably, mixed interventions were perhaps the most difficult to design and implement, primarily because they were ambitious in scope as compared to the provider-, specialist- or peer-delivered models. Mixed models required the development of two different interventions and the training of two distinct types of interventionists. Implementation preparation activities were numerous—making sure the providers accepted the intervention, understood their role, and were well trained; specialists required integration into either the clinic itself because they were newly hired or integration into their new department charged to address this issue. In both cases, it was not clear that the providers would deliver their portion of the intervention. A project director provided insight into the response of clinic staff members to the intervention project:

Again, I think that from a clinic-wide perspective, they're just anxious about the change and patients' acceptability of it and whether or not it just causes more chaos because there's already enough of that on a daily basis in a clinic because it is such a hectic place. Project Director

PCP resistance and clinic readiness for change: All sites encountered some level of provider resistance to integrating prevention and care primarily with respect to the feasibility of implementing an intervention in a busy routine clinical encounter. Provider concerns were related to clinic

Providers are very resistant to change. Our providers already have a huge amount of responsibility. We used to have 30 and 60-min appointments. Now they're 40 and 20 min. They have a bunch of additional responsibilities and now we're adding more to their plate. And they get frustrated because there is really not a process in clinic where they are approached and asked for their input on addition of responsibilities. It basically is decided and delegated that this is what's gonna happen and this is what you will do, which, as you know, doesn't engender a bunch of support and high morale. It's basically like, okay, well, we just have to do it because we've been told to do it. So, there's a barrier there, because it wasn't something that they initiated. Again, I think a lot of the providers probably see that the project would be a really great program. I think that they get a bit turned off as soon as they hear that there's more work for them. And I really have tried to be careful about letting 'em know, it's really not so much more work. You're looking at a four-question, we're giving you the information so that you know immediately where [and] what to base your prevention intervention message on. Chances are good that if you even get a 30-s prevention intervention message in with your clients, that is something. Project Director

In one location, the PI (a non-MD) appeared to have no power to persuade the providers to participate in the intervention; the trainings were poorly attended; and providers generally expressed reluctance in engaging in prevention counseling, since they had a pre-existing role as an interventionist. In both cases, it was not clear that the providers would deliver their portion of the intervention.

Unstable work force and structural upheaval: Staff turnover (unrelated to the project) posed a significant challenge among 3 of the 5 hybrid interventions. One site faced a complete turnover in provider staff, a turnover in PIs while the entire organization of the clinic was simultaneously undergoing massive re-structuring. New staff needed to be hired, trained, and then integrated into the clinic and research practice.

Overcoming the challenges: Among the mixed interventions, those most successful in overcoming provider resistance followed a process of building buy-in through a series of meetings (including the provision of food) to educate them about the project and to listen to

their concerns. One site made plans to train support staff to of the peer interventions included a detailed modular alleviate the tension and help foster clinic-wide support for curriculum for the peers to follow. In two of the three the intervention. Sites that had endorsement from the clinic interventions, these curricula were computerized presen- leadership and strong presence of a PI facilitated the uptake tations, which the peer would guide the patient through. of the prevention interventions.

Peer-Delivered Interventions

Intervention Description and Rationale

The rationale for using peers as interventionists in three locations varied by site. Two sites perceived that the intent of the intervention was beyond the scope of what a physician could achieve during a routine clinic encounter. For one, using peers was a better fit with their patient population because of issues related to stigma and shame, which prevented many patients from disclosing their HIV status to sexual partners, family members or friends. Both sites felt strongly that having peers provide information would be more effective, and that credibility and trust would be higher with peers rather than a physician or specialist. The interventions at these two sites focused on basic educational information on HIV/AIDS as well as skill-building around condom demonstration or role-playing condom negotiation and disclosure of HIV status. The third peer site rejected the use of physicians as interventionists because they did not want to burden the physicians with intervention activities. The PI below described his decision to minimally involve physicians in the intervention:

So knowing the culture of the Clinic, we kind of thought that trying to train the physicians themselves or the nurses to deliver prevention intervention would meet lots of obstacles. We felt that we had to do something that would involve referring people but would be as seamless as it possibly could, so that we would get people while they were in care. PI

HIV prevention did not appear to have a significant prior presence among the three sites implementing peer-based interventions. The PIs characterized the level of HIV prevention in a particular way—they unanimously stated that providers were focused on providing “good care” and did not have time to attend to prevention issues. Furthermore, in two of the three sites, the PIs felt that prevention was something that was notably missing and could optimally be filled by hiring a peer counselor.

Prevention Concept, Intervention Content and Tools: Peer Interventions

Similar to the interventions delivered by specialists, the peer-based interventions were largely patient driven and conceptually comprehensive. For practical purposes, each

This allowed the intervention designers careful control over the content of the intervention, while having the benefit of peer delivery and support.

Overlapping content areas among the peer interventions were few, primarily because each clinic addressed the needs of a distinct patient population. The clinic working with urban gay men took care to address complex sexual issues openly, to not stigmatize HIV-infected gay men’s sexuality, and to provide harm reduction strategies related to sex. The other two sites, working primarily with ethnic minorities, provided more educational information about HIV and “safer sex.” Medication adherence was a primary topic for one intervention; and managing stress was addressed in yet another. The format and timing of the peer-based interventions were also distinct (see Table 2). Each intervention took place near the clinic, but none were located within the clinic.

Implementation Challenges and Resolutions

Hiring, training, and supervising: The challenges of implementing peer-based interventions mainly centered on staffing and training. Locating and hiring peers was time-consuming in two of the three projects. Sites needed to determine who qualified to work as a peer with their patient population. All three sites hired peers who were current or former clinic patients even though initially they sought to hire from the general community. Peer training was intensive and in most cases needed to extend beyond the scope of preparing to implement the intervention curriculum to include research and ethical concepts, policies and procedures. In some cases, this was challenging because peers identified with their community and were eager to advocate on their behalf. At times, they described feeling constrained by having to follow a research protocol and curriculum. Sites working with disenfranchised patients in two of the three locations faced unique issues when hiring a peer. While it was important that the peers could relate to patients, peers potentially shared the same structural constraints that impacted their patients, e.g., poverty and racism. When hiring and retaining peers, one site struggled with human resources issues, such as substance use, lack of experience in the workplace, and balancing work responsibilities with private life. A project director described the challenges associated attempting to hire someone with a resource poor background:

The level of chaos in our patient’s lives is striking. Somebody gave me contact information [of a potential

hire]. This is a great guy, by the way, who we were ready to hire, and has been a patient here for a long time. So you know, adherent to medications, doing well, that sort of thing, but he was moving. He can't afford a cell phone—he gave me his mother's telephone number, said, if you need to reach me in the next week to set something up, call my Mom's house. I call Mom's house. Mom says, I don't have a pen right now. Can you call me back in twenty minutes? ...Can you just hold the job for him? Project Director

Partnering with peers: One of the greatest advantages to hiring peers as interventionists was having peers provide a valuable input on the curriculum and offer advice on recruitment. In order for peers to provide honest feedback and intervention staff had to cultivate a sense of partnership with the peers and work to minimize the power imbalance that may have prevented the hired peer from providing constructive criticism of the project because the job provided them with needed resources, i.e., a salary. Establishing clear roles and expectations increased rapport among researchers and peer-interventionists. At that point, researchers had built-in community advisors to reflect on the project materials and provide important feedback on the sensitivity, use of language, understandability and flow of the curriculum. A co-PI described the value in partnering with a peer:

And we bring her in every so often to ask her for advice and we ask her questions. And since she's worked on other projects, she has a good feel for some of the issues. She likes it. She really is, she's really, I think, more representative of peers, of what you'd find in a regular clinic. And so I really like having her around because I think it keeps us real. She will make us stay real. Co-PI

This type of cross-fertilization between peer and researchers was echoed by the peer below. In this case the peer described his role as an advisor on the development of the intervention curriculum:

So far, my role has been, well, just getting to learn more about it, more being able to talk about it. And giving input on the workbook, the modules that we're creating, trying to give input to that. One of the things that they want from me is to make sure that this reflects, because my past work and because I know so many people in the community, that it's in a language that's appropriate, that's user-friendly and those types of things. So, a lot of what I've been doing recently has been looking at what's already been written and adapting it and looking at it from that perspective from—I could very easily be a consumer coming in, you know. Does this make sense? What is the flow line here? Is the language they're using too technical

and it's gonna be off putting to people. They're not gonna respond. So those are the things that primarily I've been working on, and just trying to get up to speed on what research is and how it's done. Peer

Discussion

We found that implementation was most difficult in locations that utilized providers to deliver the intervention for two reasons. Successful implementation required changes in providers' clinical practices as well as a concomitant willingness on the part of patients to openly and honestly discuss risk with their providers. Among the specialist and peer-delivered interventions, patients shouldered the burden to show up to additional appointments and engage in the prevention counseling process. In comparing the provider-delivered interventions to the mixed interventions, we noted that the providers charged to be the sole interventionists were groomed over a longer period of time and reported a higher level of acceptability than the providers in the mixed interventions. This may indeed be perfectly logical, however it illustrates the conditions needed to fully incorporate providers as partners in prevention. In focusing on complying with the CDC guidelines to integrate prevention and care, researchers may have inadvertently misjudged the level of provider interest and downplayed or overlooked provider concerns related to feasibility to implement an intervention that relied heavily on them as key players. Another feature of the mixed interventions that contributed to implementation challenges was that they tended to be new collaborations of behavioral and clinical service providers. The lack of official authority and personal relationships between the intervention leaders and the providers contributed to the providers rejecting the intervention and failing to implement their portion of the counseling. Comparing acceptability between the provider-delivered vs. provider + specialist-delivered interventions illustrated just how crucial it was to build rapport with providers and attend to the unique issues that affected their ability to participate in behavioral interventions.

Common Elements of Successful Implementation

While we do not yet know what the behavioral outcomes of these interventions will be, we can draw conclusions about what factors must be taken into consideration in the design and initial implementation of integrated HIV prevention programs. We identified the following common elements that must be in place to successfully implement complex behavioral interventions in clinical settings:

Internal Leadership and Authority to Overcome Resistance and Foster Interest and Motivation on the Part of Clinical Providers and Clinic Staff

Adequate Attention to Creating Flow between Clinic Practice and Intervention

Establishing the logistics of how, when and where patients Any model that requires PCPs to deliver some kind of would complete a risk assessment, be referred and scheduled standardized assessment and counseling demands buy into, receive the intervention as well as follow up counseling from the providers, as well as someone in a position of enforcing, all without disturbing the clinic flow in over power to enforce the change in clinical practice. Sites burdened, facilities was far from a mundane detail. Con-working with providers spent significant amounts of time, concerns about disruption to the clinic flow were primary in staff, and money to convince the providers that (1) there the mind of the clinic staff, even if the intervention was to was a need for HIV prevention counseling within their be delivered by a dedicated staff person in an off-site practice, (2) providing behavioral counseling was an location. Specialist, peer and mixed interventions required appropriate role for a PCP, and (3) prevention counseling greater effort to ensure that staff, protocols and physical can be effective and conducted in a short timeframe. Prospects were in place to accurately channel the patient provider resistance was present in all sites ranging from through the intervention. In this regard, provider-delivered concerns about clinic flow to ideological objections to interventions were slightly less complicated. Aside from behavioral counseling of any kind. Of foremost importance determining best practices concerning risk assessment was the enthusiastic and public support of the medical delivery and communication of results to the provider, all director. At least five of the sites that included providers other components then took place in the course of the had the advantage of the Principal Investigators also being regularly scheduled medical visit.

the medical director, recipient of research funding, or

holding some other position of relative power in the clinic. *Ongoing Training within the Clinic that can Address*

These persons were able not only to endorse the intervention, but to enforce a change in the clinic practice. *Clinician and Staff Needs as Prevention Programs become*

a Regular Part of the Care

There were sites that chose not to involve providers as

interventionists because they could not gain their support Clinics developed and implemented their own trainings or

relied on local AIDS Education and Training Centers

(AETC) or other professionals to deliver training on or off

site. Primary care physicians were the most difficult group

to train since they were often far more numerous than the

Without these shared beliefs by the majority of clinical specialists or peers for whom attending an off-site training staff and patients, clinic-based PwP may not be feasible was feasible. The clinics had to be shut down, or providers "Successful" sites, defined by the high level of interest asked to attend after-hours trainings. Few clinics could among clinic staff and least amount of friction implementing the intervention, conducted formative research through most behavioral counseling trainings lasted two to with clinic staff and patients to determine the acceptability three days. Principal Investigators all wanted more training of different kinds of interventions, and to determine the designed specifically for health care providers.

risk behaviors that warranted attention. Formative research

included one-on-one interviews, written surveys, focus

groups, consultation with community advisory board, and Lessons Learned and Conclusion

or ongoing feedback sessions with interventionists and

clinic staff during the intervention development phase. This article describes the challenges and resolution of

They met with staff to review the need for a PwP-focused challenges associated with the implementation of complex

intervention within the clinic. Researchers presented data on HIV prevention behavioral interventions in clinical set-

on rising STD rates, particularly powerful were data pre-trials. We hope to draw attention to the distinct difficulties

sented from within their own clinics. They reviewed associated with provider-delivered interventions via

studies on rising rates of reported risk behavior among the relatively minimal barriers to implementing interven-

people with HIV and, where applicable, presented effects with specialists and peers. The most problematic as-

tiveness data on the intervention models they had selected aspects of implementing the specialist and peer interventions

However, at the time these models were developed, very were recruiting and retaining patients. In these interven-

little effectiveness data for PwP was available, and many times, the burden to show up for sessions separate from the

researchers had to ask providers to make a leap of faith to clinical visit fell to the patient. Whereas in the provider

agree to participate. delivered interventions, the providers had a captive

audience, the patient would come to see them. However, we argue that the advantage of providers routinely intervening with patients must be weighed against the disadvantages associated with training and motivating providers to undertake prevention discussions.

The goal of these demonstration projects is to determine which, if any, of the interventions facilitate HIV risk reduction. Our preliminary findings illustrate that implementation of each intervention model was accompanied by obstacles great and small, as well as opportunities to successfully incorporate PwP into care settings. Based on our research, there is no one model that will both function and be accepted in every clinic. Successful integration depends on the complementary fit between the intervention model and the clinical setting. The importance of assessing the feasibility of whether or not a clinic has the support of providers, staff and patients, as well as the financial resources, is the first step in determining the potential success of implementing an intervention.

As Prevention with Positives increasingly becomes standard of care in publicly funded HIV care settings, medical directors will have to make choices about how to best integrate prevention and care. Different models may present different outcomes; no one size fits all; and this article contributes to an understanding of what is potentially gained or lost in selecting one model over another. Our findings, which focused on the decision-making and operationalization of interventions in 15 diverse clinics, provide insight into this complex process of determining an appropriate intervention based on local clinical environment and the local patient population. Developing interventions that resonate with the patient population and the clinical environment will lead to great willingness from and meaningful experience for participants.

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