AIDS Behav (2008) 12:978–988
DOI 10.1007/s10461-008-9392-2

ORIGINAL PAPER

The Challenges of Assessing Fidelity to Physician-Driven HIV Prevention Interventions: Lessons Learned Implementing Partnership for Health in a Los Angeles HIV Clinic

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Published online: 22 April 2008

Abstract Documenting fidelity to HIV prevention interventions is critical to ensure consistency in intervention implementation and necessary for measuring intervention exposure and, ultimately, outcomes. Significant variation from prescribed protocols or inconsistent implementation can jeopardize the integrity of evaluation research and render outcomes uninterpretable. There is increasing support for HIV prevention models targeting seropositive individuals designed to be delivered by physicians during clinic visits. Assessing fidelity to physician-delivered interventions that occur during clinical exams present unique challenges. This paper presents findings from various data sources designed to track intervention fidelity and exposure to the Partnership for Health intervention, a physician-delivered HIV prevention intervention implemented in an urban community HIV clinic. We present findings from chart abstraction data, patient surveys and exit interviews, and provider qualitative interviews. Lessons learned and recommendations for maximizing the accuracy and validity of fidelity assessment in future evaluations of HIV prevention interventions in primary care settings are considered.

Keywords HIV prevention · Seropositive patients · HIV/AIDS · Primary care · Fidelity

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Introduction and Background

With dramatic improvement in the health outcomes of people living with HIV/AIDS (PLWHA) being treated with anti-retroviral therapy (ART), prevention efforts have shifted from an almost exclusive focus on seronegative individuals to refocus on the risks of transmission and re-infection among seropositive individuals. PLWHA, now living longer and healthier, are demonstrating they are as likely to engage in the same HIV risks as those who are not or do not know they are infected (Erbelding et al. 2000; Janssen et al. 2001; Kalichman et al. 2001; McGowan et al. 2004).

The standard of clinical care for PLWHA is quarterly or bi-annual examination. With complications, PLWHA access clinical services far more frequently. The fact that in-care PLWHA utilize the health care system regularly presents a unique opportunity to focus on the clinical visit as a forum for ongoing and reinforced dialogue related to HIV risk and prevention. Certainly, physicians have proven to be effective advocates of prevention with respect to other health risks such as cigarette smoking, alcohol consumption, diabetes, and diseases associated with being overweight (Calfas et al. 1996; Cornuz et al. 1997; Marks et al. 2002; Ockene et al. 1991, 1999). Indeed, there is emerging evidence that physician-based prevention efforts can be effective in preventing seropositive patients from engaging in sexual and drug-using risk behavior, and debunking seropostive patients'

misconceptions about risks of transmission and reinfection (Fisher et al. 2006; Richardson et al. 2004). In recent years, federal funding has supported efforts to develop, evaluate and eventually replicate promising physician-driven HIV prevention models (CDC 2003). However, identifying evidence-based HIV prevention models targeting seropositives in the context of clinical care have been slow in coming given that ART emerged in the mid-1990's.

In 2002, the CDC launched the Diffusion of Effective Behavioral Interventions (DEBI) project as a mechanism to transfer, support, and disseminate evidence-based HIV prevention models to widespread community practice (Collins et al. 2006). Since the DEBI initiative was launched, and as the number of DEBIs increase, CDC funding for HIV prevention has been increasingly tied to the expectation that DEBI models are proposed. To date, most DEBIs have been designed to take place in the context of community-based organizations and social service agencies. Thus far only one DEBI, Partnership for Health (PfH), targets the physician as the agent of intervention with HIV seropositive patients and is designed to take place in the context of routine clinical care.

In recent years, the Health Resources and Services Administration launched a demonstration project through their Special Projects of National Significance (SPNS) initiative examining the viability and efficacy of prevention models targeting PLWHA designed to be delivered in the context of primary care settings (Malitz and Eldred 2007; Morin et al. 2004). At this juncture, it is unclear which models demonstrate the greatest promise.

In spite of the promise of physicians engaging their patients in one-on-one discussions about HIV infection risks and risk reduction, mobilizing physicians to assume an active prevention role has proven to be challenging both with seronegative and seropositive patient populations (Epstein et al. 1998, 2001; Morin et al. 2004). Despite guidelines recommending that physicians integrate prevention into the care of seropositive patients, there is evidence that discussions related to infection risk and risk reduction occur inconsistently (Aberg et al. 2004; CDC 2003; Golin et al. 2004; Morin et al. 2004). Discussions related to disclosure of HIV status to sexual and drug-using partners are far less likely to occur (Marks et al. 2002). While studies reveal that HIV care providers in practices with greater numbers of seropositive patients are more likely to deliver prevention counseling, there exist significant individual and structural barriers to risk reduction counseling in these settings. Time constraints, reimbursement concerns, discomfort with discussing risk behavior with patients, inadequate training, and resistance to embracing HIV prevention as a physician's role are just a few of the common barriers that have already been identified (Golin et al. 2004; Marks et al. 2002; Morin et al. 2004; Wenrich et al. 1997).

Implementing and evaluating interventions that target physicians as interventionists presents unique challenges as well. To be successful, physician-initiated interventions often require that providers adjust their clinical routine and that prevention becomes both philosophically and administratively integrated into the clinic environment in which the intervention takes place. Assessing how and if prevention communication is occurring is especially problematic. Provider–patient communication occurs in private, which necessarily constrains objective assessment (e.g., observations or recordings) of providers' fidelity and patients' exposure to prevention discussions taking place during a clinical exam. Indeed, studies focusing on physician–patient communication have used video and observational tools to assess the content and style of physician interactions with patients (e.g., Barfod et al. 2006; Keitz et al. 2007; Koropchak et al. 2006; Sleath et al. 2008). Generally, these studies have occurred in controlled environments with small patient samples. However, employing these methods as an evaluative tool to track intervention fidelity and exposure with a large patient sample in busy practices for a sustained study period is not feasible in terms of cost, clinic acceptability and inevitable patient consenting requirements. Therefore, assessment of what occurred and the length of time spent discussing HIV prevention can only be determined by physician or patient self-reports of what occurred. Recall may be compromised by the element of time, distraction by competing concerns such as stress or other acute clinical problems, or a misunderstanding of what prevention messages meant. Yet, before it is possible to measure the success of an intervention, a first critical step must be to establish with confidence the extent to which individuals targeted for the intervention are exposed to the intervention as designed.

The DEBI models are structured to address this issue of fidelity measurement. So that the integrity of a DEBI can be maintained while ensuring that it can also be adapted to a variety of environments and diverse populations, each DEBI is defined by a set of general core elements. These core elements may relate to the interventions' structure, e.g., amount of time spent on intervention, who delivers the intervention, and in what context, or to its content, e.g., how to address and frame central themes and theoretical framework of the curriculum or HIV messages. Generally, adherence to core elements represents intervention fidelity to the DEBI model. However, even within the DEBI scheme absolute adherence to all core elements is seen as a goal that may not always be possible in diverse settings.

This paper will focus on experiences evaluating the physician-initiated DEBI, Partnership for Health (PfH) HIV prevention intervention, implemented at an East Los Angeles community HIV clinic as part of the HRSA-funded multi-site SPNS demonstration project, *Prevention*

with Positives in Clinical Settings (PwP). We will discuss the challenges this site encountered evaluating PfH in the context of a busy urban clinic, efforts that were made to overcome these challenges, and the implications of these experiences to the replication of other physician-driven HIV prevention models. The specific focus of this discussion will be the challenges of tracking and measuring fidelity with and exposure to the PfH intervention as it was designed to be implemented and how it was integrated into the clinic's routine and practice. We do not discuss findings related to patient outcomes. Instead, we share our quest to obtain accurate and valid assessments of patients' exposure to PfH prevention messages, of providers' delivery of the PfH intervention as trained and consider the extent to which these experiences may be inherent to other physician-delivered prevention models. We will highlight the unique structural challenges and opportunities related to evaluating physician driven HIV prevention models, engaging physicians as interventionists, and lessons learned that may be helpful for future clinic-based evaluations. The experience we relate underscores the importance of developing strategies to track and measure fidelity and exposure that are feasible, considers the structure and culture of the clinical environment, and if needed, builds in flexibility to adjust strategies and evaluation design to maximize confidence that accurate and valid exposure and fidelity data are obtained. Ultimately, uncertainty that patients are exposed to the intervention being tested undermines confidence in efforts to attribute outcomes to exposure to the intervention.

In its initial trial, the PfH intervention demonstrated that physicians can be effective agents of HIV prevention by initiating a discussion using a "consequence-framed" approach to risk assessment and targeted risk reduction counseling, and reinforced during each clinic visit (Richardson et al. 2004). Physicians are trained to quickly assess each patient's risk profile (e.g., multiple sex partners, unprotected anal intercourse) and tailor a brief, 5-min discussion about the consequences of not reducing risk behaviors, with a focus on affecting self and partner protections and disclosure of HIV status. PfH's aim is to establish a partnership between the patient and the physician to maintain health by reducing HIV risk and preventing HIV transmission. Further, during the initial trial, clinic administrative and clinical staff played a fundamental role in planning intervention training content and implementation strategies so that the intervention would be well-integrated into their clinical culture, processes and structure. Since its national dissemination as a DEBI model, PfH has been delivered in multiple clinical settings throughout the United States.

The HRSA-funded PfH trial evaluation in Los Angeles compared patient outcomes of one clinic selected to implement PfH to outcomes of a comparison clinic selected for its similar patient census and demographic characteristics. While clinic staff were not involved in any of the phases of this adaptation of the intervention, all clinic staff at the intervention clinic received the 4-h PfH training. Each staff member also received a training manual to which they could refer to as they implemented the intervention with their patients. Eight booster trainings were conducted over the next 18 months to train new staff, reinforce PfH intervention principles, and address challenges of implementation. The multi-method evaluation included a series of computer-assisted surveys conducted with seropositive patients recruited at each clinic at baseline pre-implementation, and at 6-, 12- and 18-months following the initiation of the intervention. Additionally, all clinic providers completed a survey every 6 months and key clinical staff participated in semi-structured qualitative interviews 1 year after the intervention launch. A "prevention prescription" pad filled out by the physician was designed as the primary method for documenting provider fidelity and patients' exposure to the intervention, and served as a prescription for preventive action for patients once they left the clinic.

Implementation and Evaluation

Clinic Characteristics

Founded in 1989, the intervention clinic is the largest comprehensive provider of HIV care which offers 12 service sites in eastern Los Angeles County. Its clinics offer outpatient medical services, HIV counseling and testing, substance-use treatment, treatment advocacy, case management, mental health and social support services. The clinic participating in the intervention serves approximately 500 clients a year, with a patient population that is predominantly Latino (85%). The predominant risk factor for HIV among patients was sexual, with over half (55%) of the clinic patients self-reporting as men who have sex with men and 25% as heterosexual men. Seventy-five percent (75%) are between 25 and 44 years of age with less than 4% 24 years or younger. Most patients are male (88%).

A review of key dates and events that occurred during the course of the PfH intervention and evaluation period may be helpful to understand the context in which implementation and evaluation of PfH occurred. As depicted in the timeline in Fig. 1, the PfH trainings took place in September 2004. The intervention clinic held two trainings; half of the staff attended one, while the other half attended the second training 1 week later. This allowed the clinic to continue providing patient care rather than to cancel a half-day of clinic care. Eight booster trainings followed within a year of the initial trainings. A final booster training was

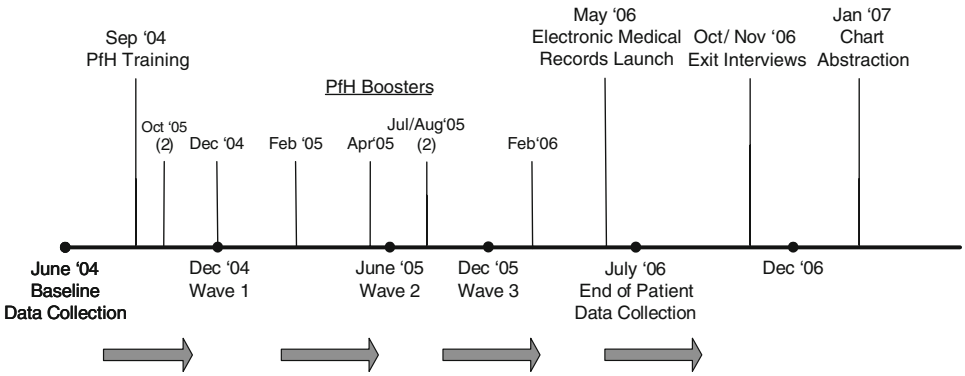


Fig. 1 Intervention and evaluation timeline

offered in March 2006. Baseline patient and provider evaluation data collection began in June 2004. Data collection ended in June 2006. In May 2006, 2 months before data collection ended, the intervention clinic implemented an electronic medical record (EMR) system which included a prompt at each visit reminding providers to assess risk and engage in prevention discussions.

Measuring Intervention Fidelity and Exposure

Two primary methods were originally designed for tracking and measuring fidelity and exposure to the PfH intervention: measures included in the patient survey that solicited reports of having engaged in partner disclosure discussions with their provider in the past 6 months and prevention prescription procedure. Semi-structured interviews with physicians offered insight into challenges they faced delivering the PfH intervention, obstacles to discussing HIV prevention during clinic visits, and barriers to documenting prevention discussions using the prevention prescription pad. Mid-study concern that these data were not yielding valid measures of exposure compelled the evaluation team to employ alternative methods to track intervention delivery—abstraction of study patient medical records and a patient exit interview, which were conducted in the last year of the study. These methods and findings are described below.

Original Methods for Measuring Fidelity and Exposure

Patient Survey

A cohort of 112 patients was recruited from the intervention clinic to participate in the PfH evaluation. The evaluation team administered a computer-assisted survey to study patients before the PfH intervention was launched (baseline) and patients were interviewed again at intervals of 6-, 12- and 18-months. Intervention exposure was measured using two dichotomous questions—in past 6 months have you received (1) counseling about disclosing your status to your sex partners, and (2) a prevention prescription from your physician.

Patient Survey Findings

At each follow up, patients were asked if during the previous 6 months their primary healthcare provider discussed disclosing their HIV status to sexual partners and if their physician had given them a prevention prescription. As seen in Table1, while patients reported frequent clinic visits, few reported receiving counseling about disclosure of HIV status to sexual partners (27% at 6 months, 12% at 12 months, and 11% at 18 months), and fewer still reported having received prevention prescriptions (11% at 6 months, 9% at 12 months, and 10% at 18 months).

Prevention Prescriptions

All intervention site physicians received a pad that simulates a traditional medication prescription pad in format and they were trained to fill out a prevention prescription on the pad once they had completed a prevention discussion with patients. The prescription pad was in triplicate form. One copy of the form was kept in the patient's chart, one given to the patient as a prescription for preventive action and one was collected by the evaluation team to be linked to study patients' survey data permitting analysis of intervention "dose". All prescription pad forms included the provider name, date, patient ID, the prescribed prevention message and the amount of time (in minutes) spent discussing HIV risk and prevention. All patients at the intervention clinic were to receive prevention prescriptions to "blind" the physicians to patients who were recruited to participate in the study. The prescription forms collected by the evaluation team were entered into the study database and linked to the patient survey data by patient ID.

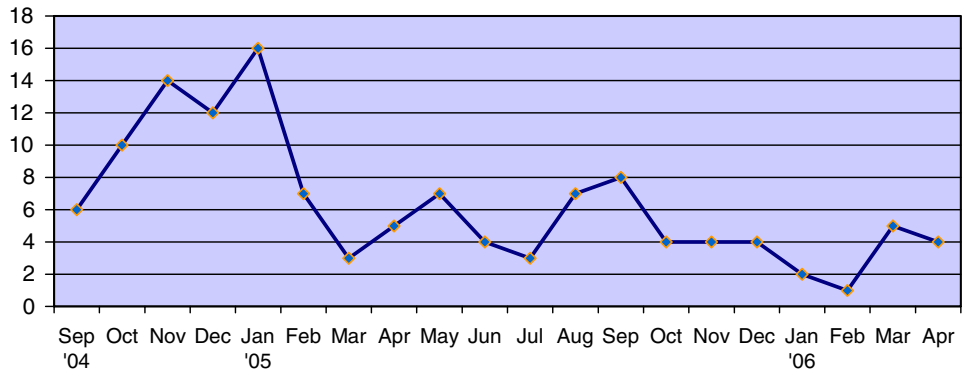
Prevention Prescription Findings

During the 2-year study period, study patients received 126 prevention prescriptions. As depicted in Graph 1, patients received most prevention prescriptions in the first 4 months of the study, with a peak number of 16 prescriptions filled

Table 1 Patient survey data: exposure to intervention

	Baseline $N = 111$ (%)	Wave 2 $N = 82$ (%)	Wave 3 $N = 67$ (%)	Wave 4 $N = 47$ (%)
Clinic utilization				
Attend only one clinic for all health care (last 6 months)				
No	19 (17.1)	18 (22.0)	24 (35.8)	11 (23.4)
Yes	92 (82.9)	64 (78.0)	43 (64.2)	36 (76.6)
How many visits were HIV-related medical care (last 6 months)				
N	92	64	43	36
Mean [*SD*]	7.5 [7.9]	7.4 [7.5]	6.7 [6.2]	5.9 [4.9]
Range	0–6–60	0–6–48	1–5–30	1–5–24
Intervention exposure				
Did your PHCP talk with you about telling your sex partner you are HIV+?				
No		60 (73.2)	59 (88.1)	42 (89.4)
Yes		22 (26.8)	8 (11.9)	5 (10.6)
Not asked	111 (100.0)			
Did your PHCP give you a prevention prescription?				
No		73 (89.0)	61 (91.0)	42 (89.4)
Yes		9 (11.0)	6 (9.0)	5 (10.6)
Not asked	111 (100.0)			

Graph 1 Number of prevention prescriptions received by patients by month



in January 2005. Within 2 months, the number of prescriptions collected dropped to well below half of the number that was collected in the peak month. This rate was maintained until April 2006, after which no other prevention prescriptions were completed. According to prevention prescription data, physicians noted spending an average of 2 min discussing prevention with patients.

These findings raised questions about whether or not physicians were delivering prevention messages despite continued booster trainings and concern that study patients were not being exposed to the intervention. Interpretation of these findings was difficult. It was unclear whether the few prescriptions collected meant that physicians were not delivering the intervention or that they were delivering the intervention but not filling out the prescription form.

Patient data were no easier to interpret. Patients' reports about the frequency of discussions required patients to recall events that took place during an examination over a 6-month period when it is likely that their primary focus might have been their immediate healthcare needs. Uncertain that patients' self report was a reflection of poor recall or that physicians were truly not delivering PfH as it was designed, the study team developed alternative strategies that might provide a more accurate and valid assessment of exposure and fidelity.

Alternative Methods for Measuring Fidelity and Exposure

Chart Abstraction

Analysis of semi-structured interviews with intervention clinic providers and informal discussions with the clinic's Medical Director, revealed that if prevention discussions occurred during a clinical visit, physicians would be more likely to document these discussions in the patients' charts,

which was standard clinic protocol, than to use the study's prevention prescription pad. The clinic's standard medical chart includes a field physicians were trained to check if any discussion occurs related to risk assessment, HIV counseling and education, condom use, or employing safer sex methods.

Consequently, the evaluation team created a chart abstraction tool designed to extract the following information from patients' charts: day and time of each clinic visit (excluding visits for laboratory or mental health), type of visit (scheduled, walk-in, other), provider-type seen, whether or not HIV prevention or risk reduction was discussed, type of prevention message delivered and level of intensity of message.

In January 2007, two clinic staff members were trained to abstract visit data from the charts of all patients participating in the evaluation study from June 2004 to January 2007. This time period covers the 3 months prior to the intervention launch and extended 6 months after the last follow-up interviews were completed. A total of 109 charts of the 112 study patients were available for review. The data were linked to the patient survey database.

To assess the frequency with which physicians documented prevention discussions in their patients' charts, the number of scheduled and unscheduled visits throughout the study period was established for each patient. The percent of visits in which prevention discussions were documented was then calculated. To track pre- and post-intervention changes in documented delivery of prevention messages, we examined monthly mean percent of visits in which prevention messages were documented in charts throughout the study period. We then performed the same monthly analysis examining monthly mean percent of visits in which prevention prescriptions were completed.

Chart Abstraction Findings

Analysis of medical charts revealed that physicians were using the charts to document prevention-related discussions and that if discussions took place, they were more likely to document discussions using charts than using the prevention prescription pad.

As seen in Table 2, there was an average of 49 visits per month by study patients during the two-and-a-half-year time period examined. Nearly all visits (86%) were scheduled appointments. Only 14% were unscheduled, walk-in visits. Throughout the review period, the mean percentage of visits in which prevention messages were documented in patients' charts was 30%.

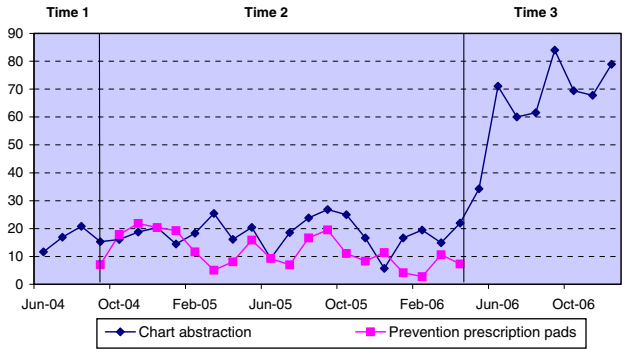
Of particular interest was the evidence of dramatic change in documented occurrence of prevention discussions within the last 9 months of the review period. The percent of visits per month in which prevention messages were documented significantly increased from a mean of 16% at start of abstraction period to 65% at end of abstraction period. Month-to-month analysis of chart data demonstrates not a gradual increase of documented prevention discussions, but rather a sharp increase that occurred in May 2006 and was sustained for the remaining study period. We concluded that this dramatic increase was attributable to the launch of the electronic medical record (EMR) system. Thus, we examined abstraction data during three separate time periods: pre-intervention period (Time 1), post-intervention period until May 2006 (Time 2) and post-EMR launch (Time 3). A one-way ANOVA demonstrated that there were statistically significant differences in the percent of visits in which prevention messages were documented among the three time periods ($df = 2$, $p < 0.01$). Further, paired comparisons revealed statistically significant differences between the three time periods. As depicted in Table 2, after the initiation of the intervention and before the EMR was instituted in the clinic, the mean percent of messages as documented in the charts increased from 16 to 18% ($p < 0.01$). A larger more dramatic increase in mean percent of messages occurred in the third time period, after the EMR was instituted from 18 to 66% ($p < 0.01$).

Analysis of the percent of visits that HIV prevention discussions took place, as documented by the number of prevention prescriptions, reveals far fewer prevention discussions during the intervention period (mean of 12% compared to 18% documented in patient charts). These findings suggest that if prevention discussions were being documented, it was more likely to be documented in patient charts than filling out prevention prescriptions.

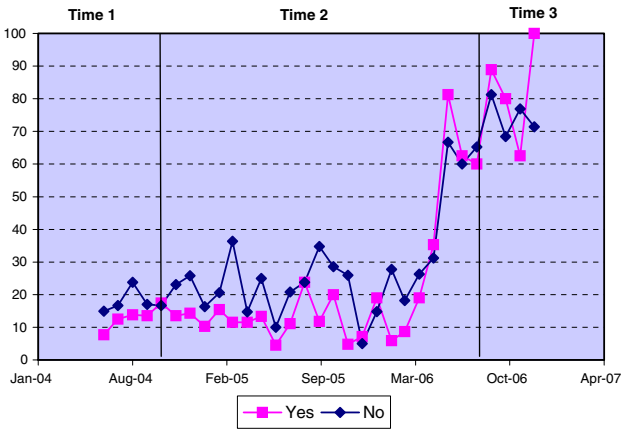
Table 2 Chart abstraction data: mean, median, and percent of visits with HIV prevention messages—June 2004 through December 2006

	Mean	Median
Number of visits per month	48.87	43.00
Number of visits received messages per month	12.39	11.00
% of visits received messages	30.34	20.34
Time 1 (pre-intervention)		
% of visits with prevention messages	16.45*	16.88
Time 2 (intervention period before initiation of EMR)		
% of visits with prevention messages (chart data)	18.21*	18.47
% of visits with prevention messages (prescription pad data)	11.77	10.87
Time 3 (post EMR launch)		
% of visits with prevention messages	65.88*	68.59

* Tests of significance for chart abstraction data are as follows: the difference in mean percent of messages from Time 1 to Time 2 (One-way ANOVA, $df = 2$, $p < 0.01$); the difference in mean percent of messages from Time 2 to Time 3 (One-way ANOVA, $df = 2$, $p < 0.01$); the difference in mean percent of messages from Time 1 to Time 3 (One-way ANOVA, $df = 2$, $p < 0.01$)



Graph 2 Percent of scheduled clinic visits patients received HIV prevention messages by month



Graph 3 Percent of visits patients reporting multiple sexual partners received messages versus patients with one or no sexual partners, by month

Graph 2 depicts the month-to-month pattern of percentage of visits in which prevention discussions were documented, according to both chart abstraction and prescription pad data. Again, after the initial months of the intervention, if a prevention discussion took place, it was more likely to be documented in the medical record than by prescription pad. For the purpose of further analysis, the graph's plot area is divided into the three time periods. The percent of visits with messages rises dramatically after the EMR was implemented, from 34% of visits per month in May of 2006 to 84% of visits per month at its peak in September of 2006. During Time 2, when eight booster trainings occurred, the percentage of visits in which prevention messages were documented remained low, reaching its highest point in September 2005 (27%) and lowest in December 2005 (6%). There is no evidence to suggest that this pattern was significantly different than the pattern found in Time 1.

Examining chart data for fidelity to the specific PfH delivery method of risk assessment and prevention messages tailored to specific risk was not possible. The chart data could only allow us to infer fidelity by examining whether or not physicians were more likely to offer prevention messages to those with known risk. Thus, we examined the chart abstraction data of patients who had reported multiple sexual partners at each wave of data collection, expecting to see higher rates of prevention messages during clinic visits for these patients. If physicians were adhering to the PfH intervention protocol, the percent of visits with prevention messages would be higher for the group with multiple partners than the percent for those patients who reported having single or no current sexual partners. On average, when assessing the entire chart abstraction period, patients reporting more than one sexual partner (57%) were more likely to receive a prevention message than those who reported only one or no sexual partners (46%). Closer examination, as depicted in Graph 3, demonstrates that there was little difference in reported prevention message delivery until the EMR was launched.

Patient Exit Survey

A short, 5 min anonymous survey was designed and administered to clinic patients immediately after exiting an examination room at the clinic. Survey measures included: type of visit (routine, walk-in, other), provider(s) they saw, whether there was any discussion of HIV prevention during the visit (e.g., safe sex, sharing needles, condom use), with whom they discussed prevention, for how long, and generally, how often was prevention discussed during clinic visits.

Recruitment for exit interviews occurred during October and November 2006. Two bi-lingual interviewers attended three scheduled HIV clinics each week during the data collection period and recruited 102 patients (who may or may not have participated in the original evaluation study) to participate in the exit interviews.

Exit Interview Findings

The exit interviews were conducted 5 months after the EMR system was fully integrated into the clinic operation. While we cannot assess the relative validity of the exit interview findings of exposure with patient survey data which was collected before the EMR, these findings corroborate chart abstraction findings that more prevention messages appear to be taking place after the EMR was launched.

The exit interview asked patients if their doctor ever talked about sex and the people they have sex with. As seen in Table 3, most reported having had at least one discussion, while 13% said they had "never" had such a discussion with their doctor. Physicians, rather than other providers, were far more likely (97%) to have seen the patient, and therefore, more likely to have delivered prevention messages. Over half (51%) of the patients who

Table 3 Exit survey findings

Description	*N*	%
All respondents (scheduled, walk-in, emergent)	102	
Who did you see today at the clinic?		
Physician	99	97.1
Registered Nurse	11	10.8
Nurse practitioner/physician assistant	4	4.0
Does provider ever talk about sex and people you have sex with?		
Half or more of clinic visits	51	50.0
Less than half of clinic visits	38	37.3
Never	13	12.7
Scheduled patient visits only	82	
Patients reporting that they received:		
"Some" kind of prevention message	42	51.2
Patients reporting their doctor talked about:		
Safer sex	36	43.9
Using condoms	38	46.3
Anal sex	21	25.6
Vaginal sex	16	19.5
Protecting partners	32	39.0
Reducing partners	21	25.6
Masturbation	5	6.1
Oral sex	22	26.8
Disclosing status to partners	18	22.0
STIs	23	28.0

came in for a regular visit reported that they received "some" kind of a prevention message during that day's visit. According to the patients, "safer sex" (44%) and "using condoms" (46%) were the main topics discussed during that prevention discussion.

Discussion

It is a key requirement of any behavior change trial that the intervention evaluated is consistently delivered with fidelity to the intervention's core elements and to the study protocol. Equally critical to valid outcome analysis is that the populations targeted for intervention receive sufficient exposure to the intervention (Dumas et al. 2001).

The core elements that define PfH as a DEBI and provide guidelines for intervention delivery address both the structure and content of the intervention. However, most PfH core elements focus on the nature and content of the physician–patient communication—building a supportive relationship with patients and engaging them in brief, consequence-framed discussions. Our experiences highlight the unique challenges we confront introducing physician-driven HIV prevention interventions such as PfH into clinical settings not only in tracking adherence to the core elements of specific HIV prevention models but in integrating HIV prevention into clinical practice in general.

This project's journey to identify valid measures of physician fidelity and patient exposure to the PfH intervention helped identify issues that can create barriers to clinics and physicians embracing HIV prevention as the standard of care and consider strategies to support physicians to engage in prevention discussions with consistency and fidelity.

The few and falling numbers of prevention prescriptions delivered and findings from patients' surveys that indicated limited exposure to prevention messages, raised concerns about how and if physicians were delivering PfH and about the validity of the measures selected to assess fidelity and exposure. Analysis of the semi-structured interviews with clinical staff provided some insight into reasons for physicians' erratic use of the prevention prescription pads. Most reported that filling them out added another step for which they were not afforded extra time, given the rapid pace of the clinic. "*It's just that it's not tracked…I think the biggest thing will be the time. I'm going to be honest with you, it's going to be the time.*" Perhaps the most significant barrier was that filling out these forms had not been integrated into existing clinic routines and protocols related to record keeping and documentation. "*…not that the prescription is difficult but it's to remember, to remind ourselves 'Oh I have to fill this out' and pull it out. I'm going to talk to you about this and here's this. But this is going to the [collection] box and this is going to get stapled... it's an extra step.*" In the final months of the study, one staff member could not remember the prevention prescriptions. She was reminded by her colleague, "*You remember the little slips of paper that always fell out of the record files?*" Well into the study period, the clinic medical director revealed that there already was an established procedure in place in which physicians were required to note prevention discussions in patients' medical charts. The clinic's existing procedures for documentation were not considered in the initial study protocol as a potential method for tracking intervention fidelity.

In the final assessment, in spite of the multiple methods ultimately used to measure fidelity and exposure, we were still left to rely on patients' and physicians' self-report. Analyses of chart abstraction data and exit interviews permitted a more stable estimate of the frequency with which prevention discussions took place. The chart abstraction provided strong evidence that physicians were systematically using the clinic's existing systems of documenting prevention discussions. Whether physicians documented prevention discussions every time they occurred and if the prevention discussions documented were framed as they were trained, remains unknown. These findings provide evidence that throughout most of the study

period prevention discussions were not taking place with the frequency dictated by the PfH intervention. This evidence is corroborated by study patients' responses to questions in the survey about whether they had received partner disclosure counseling in the previous 6 months.

However, the most dramatic finding with significant implications for future clinic-based HIV prevention interventions was the apparent effect of the EMR system on providers' documented delivery of prevention messages. The application of this structural change—a simple electronic prompt reminding providers to engage in prevention discussions—resulted in over a 400% jump in the percentage of visits in which prevention discussions were documented. Still unknown is whether this increase was due to more prevention counseling or an increase in documentation of prevention counseling. The EMR system launch occurred with only 2 months remaining in the study, seriously limiting our ability to assess the impact of increased exposure to prevention messages on the patient cohort's outcomes. Nonetheless, the exit interviews conducted 6 months following the implementation of the EMR provided evidence that patients' receipt of prevention messages mirrored the post-EMR chart abstraction findings.

With no access to exam room discussions, we remained unable to examine content fidelity, i.e., what physicians discussed and how discussions were framed, and thus we were unable to determine if physicians were delivering prevention messages in compliance with PfH core elements. The intervention specifically calls for physicians to assess patients' risk profiles and tailor consequence-framed messages to those profiles. This analysis attempted to track fidelity to this intervention by examining if patients who reported multiple sexual partners were receiving a higher rate of prevention messages per visit than patients reporting one or no sexual partners. The chart abstraction data revealed little differentiation until the EMR launch.

There is little question that integrating HIV prevention into the routine clinical care of in-care seropositive individuals represents an enormous opportunity to engage patients in an ongoing dialogue with their healthcare provider about HIV risk and risk reduction. Further, expanding the role of the physician to engage in prevention discussions tailored to patients' unique behavioral profiles can also serve to strengthen the provider–patient relationship as physicians learn more about their patients and the contexts of their lives.

However, in spite of the promise of provider-based approaches, the experience presented here underscores a few of the considerable challenges to implementing and evaluating physician-based prevention interventions that are delivered in the context of busy clinical practices. These interventions often require physicians to modify the way in which they deliver care and re-define their role. Implementation can be strained by understaffing, high patient volume, and competing patient issues. Training alone may not be sufficient to ensure that a new prevention strategy is fully integrated into clinic practices. There are real and practical challenges. There will be circumstances in which prevention messages are trumped by competing clinical concerns. Privacy and confidentiality, the hallmark of the physician–patient relationship, paradoxically challenges the evaluators' ability to know exactly what takes place in the exam room, compromising evaluation efforts to objectively assess fidelity.

There is strong evidence that physician-driven prevention is most likely to occur in clinical environments in which there is organizational support and philosophical commitment to integrating prevention and clinical care (Morin et al. 2004). Until medical training fully embraces a public health approach to clinical care, these interventions must be developed or adapted to ensure that clinical staff and organizational leadership feel ownership of any HIV prevention intervention, and that intervention protocols fundamentally fit into the routine and culture of each clinical setting. Success in mobilizing physicians to deliver a behavioral intervention during patient visits cannot be accomplished without their support and buy-in of the intervention objectives and protocols (Johnson and Remien 2003).

It is important to note that in the original trial of PfH, medical and programmatic staff in the intervention clinics played an active role in the planning process—determining appropriate message framing for their specific patient populations, identifying strategies to overcome potential barriers to implementation and developing the evaluation design. This inclusive process, though undoubtedly time consuming, may well have contributed to the trial's positive outcomes. As an increasing number of DEBI interventions are being groomed for national dissemination and replication in widely diverse environments, it is important to keep in mind all the processes and elements that came together that may have led to an intervention's success, including participation of clinic staff in the planning of implementation. While it may not be practical to fully involve clinic staff when an intervention is already designed, it is critical to engage key stakeholders in all discussions about adapting the training, implementation, evaluation design, and measurements so that it conforms to the specific structural, cultural, and philosophical characteristics of each new setting. Certainly, many of the challenges this study encountered could have been avoided with more attention paid to developing systems of documenting fidelity that conformed with and were fully integrated into existing clinic routines and procedures. These systems must be developed in full collaboration with clinic partners to maximize ownership and assure adherence.

Certainly, some of the challenges this study encountered could have been avoided or identified earlier if the intervention and evaluation staff had had a daily presence in the clinic in which the PfH intervention was delivered. Physicians in this evaluation benefited from trainings and ongoing booster trainings to reinforce the tenets of the PfH intervention, but the implementation protocol did not include mechanisms for ongoing quality assurance and monitoring fidelity to those tenets. In the original trial a clinic staff member was designated as an on-site coordinator who acted as an intervention "booster," providing day-to-day support to physicians delivering the intervention. This individual was available for impromptu and scheduled debriefing to address issues physicians and other clinic staff may have had delivering PfH. In-clinic staff dedicated to the intervention and evaluation can provide day-to-day intervention reinforcement and support to clinic staff, while also impartially observing how the intervention is being implemented and address obstacles as they occur. In this study, a clinic coordinator was designated. Though identified as the intervention "champion," this individual was not integrated into the intervention and evaluation planning and was quickly consumed by other clinic activities. Further, this position suffered two turnovers during the study period.

In this case, a structural change, the launch of the EMR system with the prevention prompt dramatically and positively altered providers' documentation of prevention discussions. EMR systems are increasingly being integrated into both ambulatory and in-patient medical care environments. These unanticipated findings underscore how powerful an EMR system and perhaps other information technologies might be utilized as a mechanism for on-going intervention reinforcement and support to providers to deliver prevention interventions. An EMR prompt can serve not only to remind providers to engage in prevention discussions, addressing process validity, but also can guide them to do so according to intervention protocols, such as assessing risk, thus ensuring content validity.

Designing valid and appropriate methods and measures of fidelity and exposure are critical to efforts to evaluate the efficacy of promising provider-driven HIV prevention models. This component of evaluation research is often overlooked and under-valued. Attention to intervention fidelity will serve not only to improve the rigor with which provider-based HIV prevention models are being evaluated, but also can serve as support to physicians and all providers of care, as they are increasingly becoming key players in the ongoing fight to curb HIV transmission.

Acknowledgements This research project was supported by Grant # H97HA01290 from the Department of Health and Human Services, Health Resources and Services Administration, Special Projects of National Significance Program.

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