Randomized, Community-Based Pharmacy Intervention to Expand Services Beyond Sale of Sterile Syringes to Injection Drug Users in Pharmacies in New York City

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Structural interventions may help reduce racial/ethnic disparities in HIV. In 2009 to 2011, we randomized pharmacies participating in a nonprescription syringe access program in minority communities to intervention (pharmacy enrolled and delivered HIV risk reduction information to injection drug users [IDUs]), primary control (pharmacy only enrolled IDUs), and secondary control (pharmacy did not engage IDUs). Intervention pharmacy staff reported more support for syringe sales than did control staff. An expanded pharmacy role in HIV risk reduction may be helpful. (Am J Public Health. 2013; 103:1579-1582. doi:10.2105/AJPH. 2012.301178)

Evidence supports the efficacy of both structural interventions targeting policy, organizational, and other sociocontextual factors and multilevel interventions targeting both individual and structural factors.¹⁻³ However, few robust studies of this type of intervention have contributed to the HIV literature.^{4,5} Amelioration of persistent racial disparities in HIV/AIDS may require structural and multilevel interventions in heavily burdened communities.^{5,6} The New York State Expanded Syringe Access Program (ESAP), a structural-level HIV prevention strategy that began in 2001 and allows nonprescription syringe sales in pharmacies to help reduce HIV transmission among injection drug users (IDUs), demonstrated improved access to sterile syringes,⁷ safe syringe disposal,^{8,9} and reduced syringe sharing.¹⁰ Minority IDUs, however, have less access to ESAP.^{6,11–14}

The Pharmacies as Resources Making Links to Community Services intervention, a largescale, randomized structural intervention targeting community members, pharmacy staff, and IDUs patronizing pharmacies in New York City neighborhoods with high proportions of minorities and significant drug activity, began in 2009.⁵ We investigated the impact of this intervention on pharmacy staff support of (1) ESAP, (2) in-pharmacy HIV testing, and (3) in-pharmacy vaccination.

METHODS

Our study methods are described elsewhere.¹⁵ Briefly, in 2009 we screened ESAPregistered pharmacies for eligibility by phone. Eligible pharmacies reported at least 1 new IDU syringe customer each month, had at least 1 new syringe customer who became a regular customer, and sold syringes to IDUs without additional requirements. Of 325 pharmacies screened, 172 were eligible, staff in 130 pharmacies completed a baseline interview (in 2009 or 2010), and 88 pharmacies were randomized by borough (Figure 1). Among those randomized, we found no differences in attrition by pharmacy-level or staff-level characteristics.

Pharmacies randomized to the intervention (n = 26) underwent group and individual training guided by a manual we developed after a pilot study; it focused on harm reduction, drug dependence, HIV prevention, and other needed services in the surrounding community, and best approaches for recruiting and providing HIV risk reduction materials to IDU syringe customers. Training sessions included role playing and were conducted quarterly to prevent protocol violations, which we assessed during random test buys. Primary control pharmacies (n = 29) did not perform intervention activities and

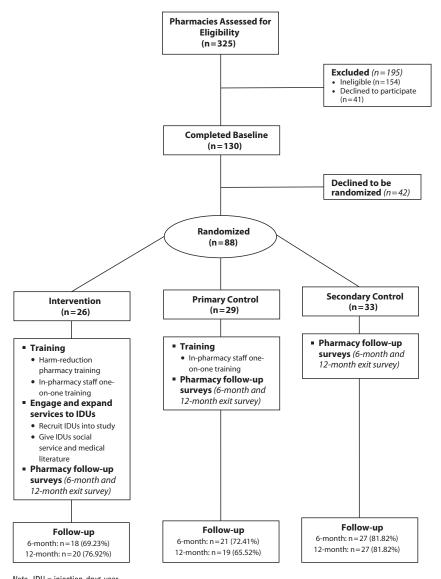
therefore received training only on IDU syringe customer recruitment. We enrolled secondary control pharmacies (n = 33), which received no training and only underwent pharmacy staff surveys, to estimate an intervention effect that accounted for potential pharmacy participation bias that might result with the primary control group. All pharmacy staff completed a 40-minute baseline, 6month, and 12-month computer-assisted interview.¹⁵ We measured intervention outcomes among both pharmacy staff and pharmacy-recruited syringe customers, but reported only pharmacy outcomes here. We terminated the participation of 1 intervention and 1 primary control pharmacy because of 2 or more protocol violations.

We examined support of ESAP, in-pharmacy HIV testing, and in-pharmacy vaccination over time by study arm and differences after the intervention by study arm. Because influenza vaccinations are becoming regularly available in pharmacies, willingness to provide vaccinations in the pharmacy may indicate greater access to these vaccinations as well as other important vaccinations such as Hepatitis B for IDUs. After baseline adjustment for support and clustering of staff within pharmacies, we estimated postintervention support levels with log-binomial regression models specifying a robust error to calculate prevalence ratios. We used SAS version 9.2 for these analyses.¹⁶

RESULTS

We found no differences in pharmacy (pharmacy type, borough) or staff (gender, position, perceived neighborhood drug activity) characteristics by study arm with exception of larger proportions of African American staff in the primary and secondary control pharmacies.

Even with high levels of ESAP support among pharmacy staff at baseline (65%–77%), support significantly increased in both intervention and primary control pharmacies following the intervention (Figure 2). After adjustment, ESAP support was significantly higher in the intervention than the secondary control pharmacies after the intervention (Table 1). We observed no intervention effect on support for in-pharmacy vaccination or HIV testing.



Note. IDU = injection drug user.

FIGURE 1—Pharmacy enrollment, randomization, and study procedures: Pharmacies as Resources Making Links to Community Services, 2009–2011.

DISCUSSION

These data suggest that a multilevel intervention approach that targets individual pharmacy staff (providing education and training) and pharmacy practice (coupling syringe sales with HIV prevention information and referrals) may strengthen the potential for an intervention effect. This is supported by (1) the significant increase in ESAP support in intervention pharmacies, where pharmacy staff were required to dedicate additional time and effort (vs control pharmacies), and (2) an intervention effect emerging in the presence of high baseline prevalence of support.

Some study limitations may have influenced our findings. Individual characteristics (other than race/ethnicity) could have been unevenly distributed across study arms following randomization. However, we explored factors that we were aware of from previous reports and found they did not differ by study arm. Selection bias could have influenced the results. For example, pharmacies with more positive beliefs about ESAP might have opted to participate, making it more difficult to detect an effect for the other outcomes under study; if true, effects might be greater in communities where support is lower. Finally, external validity is limited to pharmacies in New York City neighborhoods with high levels of drug activity.

Multilevel interventions should be considered in the delivery of HIV prevention services, particularly among populations with unmet health care needs.^{15,17–22}

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This article was accepted December 1, 2012.

Contributors

N. D. Crawford helped develop the study, performed the statistical analysis, and was the main writer of the article, to which all authors contributed. S. Amesty, A. V. Rivera, K. Harripersaud, and A. Turner assisted in study activities. C. M. Fuller originated and supervised the study.

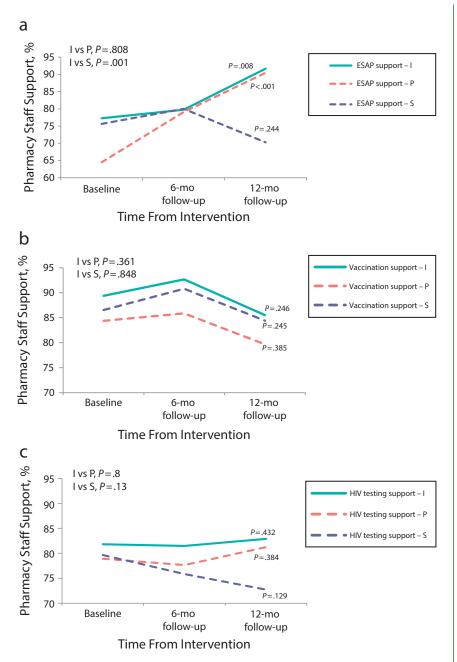
Acknowledgments

This study was funded by the National Institute on Drug Abuse (R01 DA022144) and the Robert Wood Johnson Health and Society Scholars program.

We also thank Pharmacies as Resources Making Links to Community Services (PHARM-Link) research and staff, the PHARM-Link Community Working Group (Wesley Badillo, New York State Department of Health AIDS Institute; Ann Boyer, Mount Sinai Medical Center; Dwight Brown, VIP Community Services; Nadine Ranger, Brooklyn AIDS Task Force; Jose Martin Garcia Orduna, East Harlem HIV Care Center; Laurell Lasenburg, Bronx District Public Health Office; Stuart Feldman, Touro College of Pharmacy; Camagu Tuswa, Swan Pharmacy), and PHARM-Link participants.

Human Participant Protection

Columbia University Medical Center and the New York Academy of Medicine institutional review boards approved the study. Informed consent was provided by all participants.



Note. ESAP = New York State Expanded Syringe Access Program; I = intervention; P = primary control; S = secondary control. Sample size of pharmacy staff was n = 383. These data represent pharmacy staff in 26 intervention, 29 primary control, and 33 secondary control sites at baseline; 18 intervention, 21 primary control, and 27 secondary control sites at 6-mo follow-up; and 20 intervention, 19 primary control, and 27 secondary control sites at 12-mo follow-up. *P* values represent group differences at 12-mo follow-up (I vs P; I vs S) or the trend in pharmacy support over time (individual values).

FIGURE 2—Pharmacy staff support of extended pharmacy services for injection drug user syringe customers, before and after intervention, for (a) ESAP, (b) in-pharmacy vaccination, and (c) in-pharmacy HIV testing: Pharmacies as Resources Making Links to Community Services, 2009–2011.

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TABLE 1—Adjusted Associations of Pharmacy Staff Postintervention Support for the New York State Expanded Syringe Access Program: Pharmacies as Resources Making Links to Community Services, 2009–2011

ESAP Support	Model 1, ^a PR (95% Cl)	Model 2, ^b PR (95% CI)	Model 3, ^c PR (95% Cl)
Intervention vs primary control group	1.04 (0.93, 1.16)	1.05 (0.94, 1.16)	1.05 (0.94, 1.16)
Intervention vs secondary control group	1.36** (1.15, 1.60)	1.27** (1.11, 1.46)	1.27** (1.11, 1.47)

Note. CI = confidence interval; ESAP = Expanded Syringe Access Program; PR = prevalence ratio.

^aAdjusted for clustering of individuals within pharmacies.

^bAdjusted for clustering of individuals within pharmacies and baseline differences in ESAP support.

^cAdjusted for clustering of individuals within pharmacies, baseline differences in ESAP support, and race. $*P \le .05$; $**P \le .01$.

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