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ORIGINAL ARTICLE

Essentiality of HIV testing and education for effective HIV control in the national pilot harm reduction program: The Taiwan experience

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Abstract In 2005, a national pilot harm reduction program (PHRP), which mainly included a methadone maintenance treatment program (MMTP) and a needle/syringe exchange program (NSP), was implemented in Taiwan. We conducted this study to evaluate the effectiveness of harm reduction measures on HIV control among injecting drug users (IDUs) between PHRP and nonPHRP. The data on HIV, collected from incumbent Taiwanese authorities, were analyzed for their associations, risk and protective factors with PHRP measures. While the monthly HIV incidences did not show significant differences before and after PHRP in the four areas with PHRP (Taipei City, Taipei County, Taoyuan County and Tainan County), a significant increase in the HIV incidence was found in the 21 areas without PHRP. Hence, the implementation of the PHRP did result in a significant difference in the monthly HIV incidence between areas with and without the PHRP. Mandatory HIV testing was significantly associated with the HIV incidence according to the generalized estimation equations (GEE) model. With adjustments of time period and area with PHRP, and urban area, protective factors associated with HIV incidence were: educational materials, condoms, dilution water, and alcohol sponges/swabs. MMTP contributed to a higher HIV incidence, probably due to the concurrent HIV testing upon admission. Since HIV testing was not required in the NSP, the HIV testing-dependent MMTP may

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explain the association of the PHRP intervention and an increased HIV incidence. In summary, HIV testing and education were essential for effective HIV control upon implementing the PHRP.

Introduction

It has been reported that a methadone maintenance treatment program (MMTP) and needle/syringe exchange program (NSP), two major pillars of harm reduction, are effective measures against HIV/AIDS among injecting drug users (IDUs) [1—4]. First identified in 1981, the HIV/AIDS epidemic lingers on into the 21st century. Such public health approaches have proved cost-effective to curb the spread of HIV in comparison with costly antiretroviral therapies and unavailable vaccinations [5,6]. However, doubts have also been raised regarding the effectiveness of these harm reduction measures for HIV/AIDS. For example, it has been argued that the stage of HIV epidemic and the level of HIV seropositivity among IDUs may confound the effectiveness of a NSP in the reduction of the incidence of HIV/AIDS [7]. In addition, the performance of a randomized controlled trial to test the effectiveness of NSPs in reducing the incidence of HIV has been considered impossible for reasons of ethical and logistical impediment [8].

In Taiwan, the incidence of HIV/AIDS surged in 2004 after a dormancy of two decades [9]. Prior to 2003, the HIV incidence was mostly due to men having sex with men (MSM) [10]. However, the percentage of IDUs among all addiction treatment admissions increased from 34.7% in 2000 to 63.9% in 2004, and the percentage of IDUs sharing needles increased from 4.0% in 2000 to 15% in 2004 [11]. Further investigation indicated that the major risk factors for Taiwanese IDUs were needle-sharing, followed by the sharing of dilution water [12]. A national pilot harm reduction program (PHRP), with measures including mainly a needle/syringe exchange program (NSP), a methadone maintenance treatment program (MMTP) and HIV education and counseling, was initiated in four of Taiwan's 25 administrative areas in August 2005. One year after the PHRP, the Taiwan Centers for Disease Control (TCDC) reported a dramatic 10% decrease in all new HIV seropositive cases, and a nationwide harm reduction program was subsequently implemented [13].

The report of the TCDC on the effectiveness of the PHRP in Taiwan supported previous studies [13,14]. However, after scrutinizing the data of the PHRP, we found that some other factors may also be involved in the claimed effectiveness. For example, mandatory HIV testing, which took effect in April 2004 in drug users who violated the Narcotics Control Act, could have expanded the base of new HIV cases and explained, at least in part, the surge in the incidence of HIV. In addition, so far the effects of harm reduction measures on HIV control have not been evaluated owing to the lack of an experimental/control design. Hence, the implementation of the PHRP in four administrative areas in Taiwan has provided us with a rare evidence-based opportunity to compare the harm reduction effectiveness in those areas with the PHRP to that in the other 21 administrative areas without a PHRP. For future HIV preventive purposes, it is also imperative to evaluate the factors of the PHRP that contribute to the reduction in the incidence of HIV. We therefore attempted to evaluate the effectiveness of the measures of harm reduction and their associated factors on the incidence of HIV/AIDS.

Materials and methods

Taiwan, an island country with a population of 22,770,383 in 2005, is composed of 25 administrative areas (7 cities and 18 counties). A city is defined as an urbanized area with a population of more than 300,000 residents. A county is a suburban and rural area with satellite cities or township(s) where the population is lower than that of a city.

Four administrative areas, including one city (Taipei) and three counties (Taipei, Taoyuan and Tainan), voluntarily participated in the PHRP. The PHRP was approved by the Executive Yuan (Cabinet), Taiwan, R.O.C., and was launched from August 2005 to June 2006. The other 21 areas without a PHRP therefore served as control groups. This observational study was designed to compare the change over time in the incidence of HIV in these areas of Taiwan before or after the implementation of PHRP in the areas with and without a PHRP from 2004 to 2006. The HIV/AIDS data were obtained from the national HIV/AIDS registry of the TCDC [15,16], in which physicians are requested by law to report identified cases of HIV infection and AIDS within 24 h of diagnosis. Patients' information, including name, identification card number, gender, home address, date of birth, date of diagnosis, occupation and risk factors are recorded on a case report form.

In the process of PHRP implementation, the NSP and MMTP were developed simultaneously. The NSP was established to distribute free needles and syringes, but one-for-one syringe exchange was not strictly demanded. In the NSP sites, free condoms, sterile paraphernalia including dilution water, alcohol sponges/swabs for cleaning injection sites and educational materials regarding the prevention of blood or sexually transmitted disease (STD) were also supplied. The returned contaminated needles and syringes were collected and the syringe return rate was determined as the returned contaminated needles and syringes divided by the distributed clean needles and syringes. The HIV incidence was determined as the number of new HIV cases divided by the population of the specified area per month per 1,000,000 persons.

According to the regulations of the TCDC, HIV-infected IDUs can receive methadone treatment free of charge, while HIV seronegative IDUs are charged ca. US$1600 per year for the same treatment [13]. The quantities of materials delivered to IDUs in the NSP and the number of IDUs who participated in the MMTP were also recorded. All data

regarding the NSP and MMTP were also obtained from the TCDC [15,16].

The monthly HIV incidences of the administrative areas (city/counties) were used as observations in the analysis database. Basic information regarding the city/county characteristics and the PHRP policy was also obtained as analysis covariates. To examine the impact of the PHRP on the HIV trend in Taiwan, generalized estimation equations (GEE) were adopted with Poisson as the probability distribution function and the first-order autoregressive as the correlation structure [17–19]. HIV incidences from August 2004 to June 2005 (before the PHRP) and August 2005 to June 2006 (during the PHRP) were included in the analysis. As the populations of the cities/counties vary, the weights according to the size of the cities/counties were incorporated into the statistical analysis. Analyses of the HIV incidences were performed to ensure that the HIV situations of all areas with or without the PHRP were comparable.

To investigate the potential effects (factors including mandatory screening, PHRP intervention, PHRP area, urban area and numbers of distributed clean syringes, returned syringes, patients on methadone, and distribution of condoms, dilution water, alcohol sponges/swabs and educational materials) on the outcome of HIV incidence, the univariate GEE model was first used to compute the individual odds ratio for each effect. The effects of the numbers of distributed clean syringes, returned syringes and patients on methadone, and the distribution of condoms, dilution water, alcohol sponges/swabs and educational materials on HIV incidence were further investigated by separate multivariate GEE models with the additional covariates of mandatory screening, PHRP intervention, PHRP area, interaction effects of PHRP intervention and areas and urban area. The PROC GENMOD of SAS software was used to implement the analysis of the GEE models.

In these analyses, all p values were two-sided, with the statistical significance set at $p < 0.05$. All statistical analyses were performed using SAS software version 9.1 (SAS Institute, Cary, NC, USA).

Results

The PHRP was officially initiated in four administrative areas of Taiwan in August 2005 until June 2006. Subsequently, a nationwide harm reduction program was implemented in all 25 administrative areas of Taiwan in July 2006. Of the four areas in which the PHRP was launched, the NSP was not executed in Taoyuan County during this PHRP period. Among the other three administrative areas, i.e., Taipei County, Taipei City and Tainan County, educational materials for the NSP were mostly distributed in Tainan County (Table 1). The syringe return rates were 24.63%, 12.57% and 10.52% in Taipei County, Taipei City and Tainan County, respectively. In addition, 385 individuals were admitted to six hospitals for an outpatient MMTP (Table 1). Among the 385 patients, a majority of 249 (65%) were treated in Taoyuan County.

The GEE analyses for the monthly HIV incidence trend are shown in Table 2, and no significant differences were observed between before and after the PHRP in the four areas in which the PHRP was initiated ($p = 0.89$). For the areas without a PHRP, the mean HIV incidence significantly increased by 3.69 per 1,000,000 persons. Moreover, there was also no significant difference in the monthly HIV incidence between areas with a PHRP ($n = 4$) and those without a PHRP ($n = 21$) either before the PHRP ($p = 0.38$) or after the PHRP ($p = 0.57$). A significant interaction effect ($p = 0.02$) was found between areas with/without a PHRP and the time period with/without a PHRP. Hence, the implementation of the PHRP did result in a significant difference in the monthly HIV incidence between the areas with and without the PHRP.

The GEE analyses of the PHRP-related factors are presented in Table 3. According to the univariate analyses, the factors associated significantly with the HIV incidence included mandatory HIV testing (odds ratio (OR) 2.55, 95% CI: 1.97–3.30); PHRP intervention (OR 1.53, 95% CI: 1.30–1.79); and methadone treatment (OR 7.45, 95% CI: 3.93–14.13). In other words, mandatory HIV testing since April 2004 due to violation of the Narcotics Control Act (OR 2.55) and the PHRP intervention period (OR 1.53) resulted in a significantly higher HIV incidence as compared to a lack of mandatory HIV testing or a PHRP intervention period.

With adjustment for mandatory screening, time period and administrative area with PHRP intervention, and the urban area, the protective factors associated with HIV incidence in our multivariate GEE analysis were the provision of condoms (AOR 0.86, 95% CI: 0.83–0.89), dilution water (AOR 0.93, 95% CI: 0.91–0.96), alcohol sponges/swabs (AOR 0.97, 95% CI: 0.96–0.98), and educational

Table 1 Basic PHRP measures implemented in four administrative areas of Taiwan from August 2005 to June 2006.

PHRP Measures	Taipei County	Tainan County	Taipei City	Taoyuan County	Total
NSP					
clean needles and syringes (set)	41,609 (26%)	111,165 (71%)	4358 (3%)	—	157,132
condoms (dozen/box)	1408 (20%)	4422 (63%)	1217 (17%)	—	7047
dilution water (amp)	2083 (18%)	8237 (72%)	1189 (10%)	—	11,509
alcohol sponges/swabs (pack)	2197 (8%)	22,150 (79%)	3854 (14%)	—	28,201
educational materials (package)	245 (8%)	2216 (72%)	638 (21%)	—	3099
returned syringes (set)	10,247 (46%)	11,697 (52%)	548 (2%)	—	22,492
return rate	24.63%	10.52%	12.57%	—	47.72%
MMTP					
patients	34 (9%)	79 (21%)	23 (6%)	249 (65%)	385

MMTP = methadone maintenance treatment program; NSP = needle/syringe exchange program.

Table 2 Comparison of HIV incidence among administrative areas before or after and with or without PHRP.

	Mean incidence (±SD) in Time 1	Mean incidence (± SD) in Time 2	Mean incidence difference (95% CI)	Time 2 vs. Time 1 *p* value
Areas with PHRP ($n = 4$)	11.55 ± 1.84	11.44 ± 2.17	−0.11 (−2.60, 2.39)	0.89
Areas without PHRP ($n = 21$)	9.25 ± 1.72	12.94 ± 2.07	3.69 (1.74, 5.64)	<0.0001
Mean incidence difference (95% CI)	2.29 (0.32, 4.26)	−1.50 (−3.86, 0.86)	−0.35 (−0.64, −0.07)*	
PHRP vs. non-PHRP, *p* value	0.38	0.57	0.02	

The HIV incidence was determined as the number of new HIV cases divided by the population of the specified area per month per 1,000,000 persons. The unit of HIV incidence is defined as persons per 1,000,000 population.
Time 1 = 11-month period before PHRP from August 2004 to June 2005.
Time 2 = 11-month period during PHRP from August 2005 to June 2006.
A *p* value was based on the likelihood ratio test derived from the GEE model with Poisson as the underlying distribution, and the multivariate model was adjusted by PHRP intervention period, PHRP area, and the interacting effect of these two factors. HIV incidence was adjusted by the weight variable based on the population of each area.
P values were two-sided, with the statistical significance set at $p < 0.05$.
* This mean incidence difference was also estimated based on the likelihood ratio test derived from the GEE model with Poisson as the underlying distribution, and the multivariate model was adjusted by PHRP intervention period, PHRP area and the interacting effect of these two factors. HIV incidence was adjusted by the weight variable based on the population of each area.

materials (AOR 0.73, 95% CI: 0.63—0.85, Table 3). Among these associated factors, the distribution of educational materials (AOR 0.73) had a greater protective effect than the provision of clean syringes (AOR 0.99) and returned syringes (AOR 0.98). Thus, the distribution of educational materials to IDUs appeared to have a better effect than the provision of clean syringes in the control of HIV incidence. Compared with other factors, methadone treatment

Table 3 Analysis of factors associated with HIV incidence using the GEE models ($n = 25$ administrative areas, months = 30).

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*p* value	AOR (95% CI)	*p* value
Mandatory HIV testing yes vs. no	2.55 (1.97, 3.30)	<0.0001		
Time period with PHRP yes vs. no	1.53 (1.30, 1.79)	<0.0001		
Administrative area with PHRP yes vs. no	1.14 (0.73, 1.78)	0.56		
Urban Area yes vs. no	1.03 (0.56, 1.87)	0.93		
Clean syringes per 1000 units	1.00 (1.00, 1.01)	0.69	0.99 (0.99, 1.00)	0.08
Returned syringes per 1000 units	1.01 (0.99, 1.04)	0.22	0.98 (0.96, 1.02)	0.56
Methadone per 1000 persons	7.45 (3.93, 14.13)	<0.0001	2.99 (1.28, 6.97)	0.01
Condoms per 1000 units	1.02 (0.91, 1.15)	0.72	0.86 (0.83, 0.89)	<0.0001
Dilution water per 1000 amps	1.01 (0.94, 1.07)	0.85	0.93 (0.91, 0.96)	<0.0001
Alcohol sponges/swabs per 1000 units	1.00 (0.98, 1.01)	0.65	0.97 (0.96, 0.98)	<0.0001
Educational materials per 1000 units	0.98 (0.84, 1.15)	0.79	0.73 (0.63, 0.85)	<0.0001

The monthly record of each city was considered as one observation in this analysis model.
AOR = adjusted odds ratio for mandatory screening; CI = confidence interval; OR = odds ratio; PHRP = intervention and urban area.
P values were two-sided, with the statistical significance set at $p < 0.05$.

appeared to contribute to a higher HIV incidence (AOR 2.99, 95% CI: 1.28—6.97).

Discussion

Harm reduction has been reported to be effective against HIV/AIDS among IDUs. However, the effectiveness of harm reduction remains controversial, not only because of its obscure definition and concept, but also its entanglement with drug abuse-related law enforcement/crime and lack of control/experimental-based evidence [1—4,20]. Hence, at the advent of the HIV epidemic, an evidence-based response is desperately needed [21]. The implementation of the PHRP in Taiwan provided such an opportunity to evaluate the effectiveness of harm reduction on the control of HIV.

As shown in Table 2, while the monthly HIV incidences did not differ significantly before and after the implementation of the PHRP in the four areas with the PHRP (Taipei City, Taipei County, Taoyuan County and Tainan County), a significant increase in the HIV incidence was found in the 21 areas without the PHRP. Hence, the implementation of the PHRP did result in a significant difference in the monthly HIV incidence between areas with and without the PHRP.

Although a dramatic 10% decrease in all new HIV cases was observed within a year of the initiation of the PHRP, at least two other important national policies may have affected the HIV/AIDS incidence before or during the PHRP [8,13]. As summarized in Fig. 1, two HIV screening tests were performed nationwide in illicit drug use suspects and pregnant women in addition to the PHRP. Such thorough HIV testing may have expanded the basis of HIV incidence and explained, at least in part, the surge in HIV incidence in 2005 and subsequent drastic decline in 2006. The effect of HIV testing on HIV risk behaviors and incidence among IDUs is well-documented [22—24]. As shown in Table 3, the significant association of mandatory testing with HIV incidence in the GEE analyses supports our inference that the HIV testing implemented before the PHRP in IDUs did affect the HIV incidence.

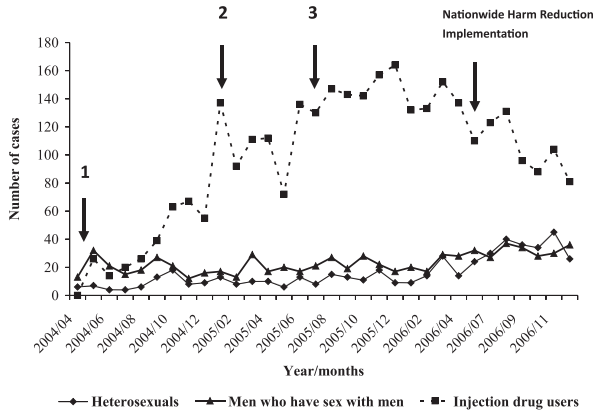

Figure 1. Dates of important national policies on HIV prevention and numbers of HIV-infected persons in three major high-risk groups reported to the Taiwan Centers for Disease Control from April 2004 through December 2006. There were at least three important policies implemented before and during the PHRP period. "1" denotes a mandatory HIV screening test, which took effect in April 2004 in drug users who violated the Narcotics Control Act. "2" represents a national program of HIV screening initiated in pregnant women to prevent mother-to-child transmission in January 2005. "3" represents the start time of the MMTP, in which only 385 patients participated. In July 2006, the harm reduction policy was fully implemented in all administrative areas of Taiwan.

Given the low MMTP coverage rate (only 385 patients were admitted for treatment among an estimated 60,000—100,000 IDUs in Taiwan, Table 1) and late stage intervention (Fig. 1) [25], it seemed puzzling that the MMTP was significantly associated with a higher HIV incidence risk (OR 7.45, 95% CI: 3.93—14.13, Table 3). Such an association persisted even after adjustment for mandatory testing, time period and administrative area with PHRP intervention, and the urban area (AOR 2.99, 95% CI: 1.28—6.97). This association could be explained by the TCDC policy that upon admission all MMTP patients were mandated to take a HIV test, which could further broaden the basis of HIV incidence [13]. Furthermore, the complimentary MMTP treatment for HIV-seropositive IDUs may also encourage these patients to participate in the MMTP. In contrast to the MMTP, the implementation of the NSP (clean syringes and returned syringes), for which HIV testing was not required, did not significantly affect the HIV incidence (Table 3). As the MMTP and the NSP were the two major measures in Taiwan's PHRP, the MMTP may be an important contributing factor that was associated with PHRP and HIV incidence (Table 3).

Using HIV incidence as the unit of analysis, and controlling for other factors associated with HIV public health policies, the distribution of HIV/AIDS educational materials to the IDU population was the most protective factor against HIV transmission among other factors associated with the NSP. In other words, HIV education and counseling assists IDUs to recognize HIV risk factors and change their behavior related to injecting drugs [26]. Our findings are in agreement with those of previous studies that indicated that appropriate education and counseling should be implemented simultaneously with the introduction of a NSP [7,22,26—29].

Our study showed that neither the distribution of clean syringes nor the quantity of returned syringes was associated with HIV incidence. In Taiwan, IDUs were required to return used syringes when they exchanged them for new syringes in the NSP. Many studies have examined the relationship between syringe sharing and HIV incidence and NSPs with different syringe dispensation policies, such as the "one-for-one", the "one-for-one-plus", the "starter pack" and the "distribution" syringe exchange programs (SEPs) [30—33]. The "one-for-one" SEP gives clients the same number of sterile syringes as were turned in by the clients [33]. The "one-for-one-plus" SEP gives clients a few more syringes than were turned in by the clients [33]. The "starter pack" SEP gives clients a few syringes and they are not required to turn in any used syringes [33]. The "distribution" SEP gives clients the number of syringes that they request, no matter how many syringes the clients turned in [33]. Bluthenthal et al. and Kral et al. reported that less restrictive dispensation polices, such as the "distribution"

SEP, have more clients and a lower proportion of reuse of syringes and sharing syringes [32,33]. In Taiwan, the syringe dispensation policy was similar to the "one-for-one-plus" SEP; thus, this restrictive dispensation policy, which may result in a lower exchange rate, may also cause negative results for HIV incidence in Taiwan.

We also demonstrated that the distribution of more condoms, dilution water, and alcohol/swabs was associated negatively with HIV incidence. A previous study reported that HIV seropositive IDUs were more likely to share dilution water (87.5%) and containers (78.2%) in Taiwan [25]. From the results of this study, we suggest that the distribution of more dilution water to avoid IDUs sharing dilution water is one of the protective factors against HIV spread. Moreover, Huo et al. demonstrated that compared to Needle Exchange Program (NEP) nonusers, NEP users had a 49% higher odds of using condoms with their sexual partners, suggesting that NEP participation may help to reduce the risk of sexual transmission of HIV [34]. The China—Vietnam Cross Border NEP distributed condoms and sterile syringes, and proved that HIV prevalence and incidence fell by half after the 24-month survey [35]. Bleach and alcohol are commonly utilized by IDUs to clean used syringes in other countries [36,37]. In addition, Abdala et al. and Flynn et al. found that bleach and rubbing alcohol to rinse syringes could significantly decrease the rate of recovering infectious HIV-1 [38,39]. Therefore, distribution of more condoms and alcohol/swabs are important protective factors in reducing the incidence of HIV and may also remind IDUs of the importance of safe sex and good sanitation.

It has been argued that at least two factors may confound the effectiveness of NSPs in the reduction of HIV/AIDS incidence, i.e., the stage of HIV epidemic may vary in areas with and without a NSP and the level of HIV seropositivity among IDUs may not be recognized [7]. Hence, we performed tests to ensure that the HIV situations of all the areas with or without and before and after the PHRP were comparable. However, there were a couple of limitations in this study. First, during the implementation of the PHRP, IDUs may have had the chance to participate in the NSP and the MMTP simultaneously, but we did not know whether the IDUs attended both the NSP and MMTP. If IDUs participated in both the NSP and the MMTP, HIV incidence may rise initially. IDUs were required to take a mandatory HIV screening test when they joined the MMTP for the first time. Hence, if many IDUs were infected with HIV before taking part in the MMTP, the incidence of HIV may increase rapidly. However, after the MMTP had been implemented for a long time, HIV incidence may not expand as a result of some protective factors including HIV education, HIV counseling, and the distribution of condoms and dilution water. Alternatively, if many IDUs participated in the MMTP during the PHRP, we would be able to estimate the effect of the MMTP on HIV incidence precisely. Second, despite extensive multivariate adjustment, the association between the PHRP and HIV incidence may be influenced by confounders that were not measured by the study instrument. These confounders include: (1) IDUs who had sterile injection equipment but did not use it — they might therefore share dilution water or syringes or engage in unsafe sexual behavior, which may lead to overestimation of the effect of the NSP on HIV incidence; (2) at the start of the PHRP, IDUs might not have received information regarding the MMTP, and consequently few IDUs participated in the MMTP, which resulted in underestimation of the effect of the MMTP on HIV incidence. In addition, despite the fact that we were not able to perform randomized grouping due to ethical reasons, voluntary participation in one quarter of the total population in these four PHRP areas with comparable initial HIV situations (Table 2) has made comparison between the PHRP and nonPHRP areas reasonably possible.

Despite these limitations, our study provides the first control/experimental-based results regarding the effects of harm reduction measures on HIV control among IDUs. Our data indicated that whereas the PHRP measures were associated with a reduction in the incidence of HIV, HIV education and HIV testing were essential for effective HIV control upon implementing these measures.

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