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Can Policy Interventions Affect HIV-Related Behaviors? A Systematic Review of the Evidence from Low and Middle-Income Countries

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Abstract

In their response to HIV, many countries have adopted and enacted policies to reduce transmission and increase HIV-related service use. Theoretically, policy-level interventions for HIV prevention have the potential to improve health behavior outcomes. These policy interventions vary in their scale, from relatively minor changes in clinical policy to major national legal initiatives. Assessing the effectiveness of HIV policy interventions is a challenging undertaking. While many policies exist and guide HIV programmes, relatively few have specifically been evaluated for their effects on reducing HIV risk taking or increasing HIV health-seeking behaviors. Thus, questions on the effectiveness of policy interventions to prevent HIV and change HIV-related risk behaviors remain largely unanswered. To address this current gap in the literature, we systematically reviewed the existing evidence on the effect of HIV policy interventions on changing HIV-related behaviors in low-and middle-income countries.

Keywords

HIV; Policy; Behaviors; Systematic review

Introduction

A vast majority of the estimated 37 million people living with HIV reside in low-and middle-income countries [1]. Worldwide, many countries have adopted and enacted policies to reduce HIV transmission and increase HIV-related service use such as routine HIV testing for pregnant women [2, 3], screening for HIV infection in tuberculosis (TB) clinics [4] or

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mandatory condom use in brothels [5, 6]. These policies often stem from recommendations from agencies such as the World Health Organization or they may be independent initiatives of a country to deal with its HIV crisis.

Theoretically, policy-level interventions for HIV prevention have the potential to improve health behavior outcomes. Policies may alter the physical and social environment or attempt to change social norms in ways that help make healthy behavior choices (e.g., condom use) the default choice [7, 8]. As such, they are believed to facilitate behavior change by reducing the role of individual decision making or by making the healthy or reduced risk behavior the socially accepted or easier choice. However, policy interventions vary in their scale, from relatively minor changes in clinical policy to major national legal initiatives. The former may have limited but positive impact, while the latter can have sweeping but sometimes unforeseen effects. Understanding the potential benefits and recognizing the potential for harm if policies are not well planned or implemented, are important for countries contemplating HIV policy interventions.

Assessing the effectiveness of HIV policy interventions is a challenging undertaking. Not all health policies include an intervention and even those that do differ in their intent and intensity. For example, a distinction must be made between policies that “nudge” people [9, 10] into choices or actions that reduce their risk of HIV infection (e.g., 100% condom policies) and policies that are principally proscriptive (e.g., prohibitions on needle syringe programmes). Second, evaluating the effect of policy interventions can conflate the effect of the policy with the effect of a behavioral intervention called for in the policy. Finally, while many policies exist and guide HIV programmes, relatively few have specifically been evaluated for their effects on reducing HIV risk taking or increasing HIV health-seeking behaviors.

Despite these challenges, evaluations of HIV policy interventions have been completed. In some cases, policy interventions have been compared across countries [11]. Other evaluations have analyzed the evolution of HIV policies within a country over time, such as evaluation studies of the shift from HIV prevention policies to HIV treatment policies within a country [12–16]. However, to date, no systematic review synthesizing the effect of HIV policy interventions on HIV-related behaviors (e.g., condom use, injection drug use, number of sex partners, treatment and health seeking behaviors) in low- and middle-income countries has been conducted. Thus, questions on the effectiveness of policy interventions to prevent HIV and change HIV-related risk behaviors remain largely unanswered.

To address this current gap in the literature, we systematically reviewed the existing evidence on the effect of HIV policy interventions on changing HIV-related behaviors in low- and middle-income countries.

Methods

Objectives

This review is a part of a series of systematic reviews and meta-analyses being conducted by the Evidence Project, which focuses its attention on evidence of effectiveness of HIV

prevention in low- and middle-income countries where continued HIV transmission and the need to direct scarce prevention resources are ongoing challenges. This project includes researchers from the Medical University of South Carolina and the Johns Hopkins Bloomberg School of Public Health. The Evidence Project has systematically reviewed multiple HIV interventions in low- and middle-income countries, including the impact of treatment on risk behavior [17], mass media [18], voluntary HIV counseling and testing [19, 20], psychosocial support for people living with HIV [21], peer education [22], condom social marketing [23], positive prevention [24], interventions to promote serostatus disclosure [25], provider-initiated testing and counseling [26], family planning for women living with HIV [27], school-based sex education [28] and behavioral counseling [29]. All reviews conducted by the Evidence Project follow guidance issued by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Statement [30].

Definition of Policy

For the purpose of this review, an HIV policy intervention was defined as an intervention in which a policy or law enacted by a local or national government or workplace was implemented with the goal of influencing HIV-related behavior change. We defined a policy as a set of standard operating procedures that were consistently applied and written or codified in some manner. To be included as a primary study, the policy had to be intentionally related to HIV. For example, policies directly related to HIV can either strive to remove barriers to safer behaviors (e.g., decriminalizing condom possession), or create barriers to unsafe behavior or “nudges” to safer behaviors (e.g., a 100% condom intervention). If a policy was related to HIV unintentionally (e.g., a war on drugs that unintentionally affected HIV prevention-related behaviors), it was coded as a background article.

Inclusion Criteria

To be included in this review, an article had to: (i) address interventions which were focused on HIV prevention, or include HIV-related outcomes; (ii) focus on interventions which included a policy or law enacted; (iii) present specific outcomes of interest (behavioral, psychological, social or biological outcomes related to HIV); (iv) take place in a developing country setting as defined by the World Bank's low-income, lower-middle income, and upper-middle income categories [31]; (v) use a study design that presented post intervention data; (vi) present a multi-arm, or pre- post-assessment of relevant outcomes; (vii) be published in a peer-reviewed journal between January 1990 and the search date of January 2013.

If it was unclear from the article whether a policy or law was actually enacted, the authors were contacted for clarification. If the authors did not respond, the study was excluded. Additionally, if the article discussed a large set of policies and programs (for example, the U.S. President's Emergency Plan for AIDS Relief [PEPFAR]), it was excluded because any change in behavior could not be attributed to a specific policy or law alone.

Studies that presented only process outcomes, such as reporting the amount of commodities sold/distributed (e.g., number of condoms sold in a condom social marketing campaign), were also excluded from the review.

Search Strategy

To identify eligible articles for this review, the following search terms were entered into five electronic databases (PubMed, CINAHL, PsycINFO, Sociological Abstracts, and EMBASE): policy OR law OR legislation OR “100% condom” OR decriminalize OR guidelines OR outlaw OR (registration AND “sex worker”) OR sanction OR tax OR (unions and agreement) OR (associations and agreement) AND (HIV OR AIDS) AND (evaluation OR cohort OR “prospective cohort” OR “retrospective cohort” OR “case control” OR “before after” OR “time series” OR control OR effectiveness OR comparison OR study OR intervention OR RCT OR “non randomized trial” OR “cross-sectional” OR “randomized controlled trial” OR “randomized clinical trial” OR “controlled clinical trial”). We also used place-specific terms (e.g., “US”, “UK”) to restrict the search to low and middle-income countries. In addition, we conducted a secondary search of reference lists of included articles as well as a hand search of four key journals: *AIDS*, *AIDS and Behavior*, *AIDS Care* and *AIDS Education and Prevention*. The secondary and hand searches were iterative processes and continued until no new studies were identified.

After removing duplicates, the initial search results were screened by a single research assistant to remove articles clearly not meeting the eligibility criteria. Next, two research assistants completed a second round of screening independently, and discrepancies were resolved through consensus. Final decisions on inclusion of articles were made after full-text review by at least two research assistants.

Data Extraction

Two trained research assistants reviewed each article identified as eligible for this systematic review using a standardized data extraction form. The following data were extracted from each article: location, setting and target group, years (period of study); description of intervention; study design; sample size; age range and gender of participants; random or non-random allocation of participants; length of follow-up; outcome measures; comparison groups; type of policy; level of policy; geographic location covered by the policy; implementers of policy; funding source; effect sizes; confidence intervals; significance levels; and limitations identified by authors and Evidence Project research assistants. The research assistants also conducted a quality assessment of each primary article. Criteria of the rigor assessment were as follows: having a cohort, control or comparison group, pre-/post-test intervention data, random assignment of participants to the intervention, random selection of participants for assessment, follow-up rate of 80% or more, comparison groups equivalent on socio-demographics, comparison groups equivalent at baseline on outcome measures.

Data Analysis

We categorized articles by the policy intervention's target population [i.e., pregnant women attending antenatal clinics (ANC), people who inject drugs (PWID), sex workers, primary

school students, and patients with TB attending health care clinics]. Articles were further categorized based on the type of policy (i.e., mandatory enforcements, harm reduction, bans, and registration and routine service) implemented among the specific target population. We did not conduct meta-analysis due to variation in study designs, measured outcomes, target populations, and types of policies.

Results

Search Results

The initial electronic database search identified 11,772 records. We found an additional 140 records through other sources. Once we removed duplicate records ($N = 1449$), the remaining 10,463 records were screened for eligibility (Fig. 1). From this initial screening, 10,297 records were deemed unrelated and removed. The full-text of the remaining 166 records were retrieved and reviewed in duplicate. Of these 166 records, 80 records were removed because they did not meet study design criteria, two were removed because they were related to studies already identified as primary records to be included in the review, and 66 were included solely as background articles. The remaining 18 articles were deemed eligible and included in this review. Of these, some articles referred to the same policy intervention in the same setting. As a result, this review focused on 15 HIV prevention policy interventions.

Description of Included Studies

Descriptions of the studies covered in this review are found in Table 1. Four studies, one each in Uganda [2], Zimbabwe [3], Botswana [32] and South Africa [33], focused on women ANC in sub-Saharan Africa. The policies evaluated were primarily Provider Initiated Testing and Counseling (PITC) and expanded HIV treatment regimens with lifelong treatment for infected mothers (Option B+) [34]. Two studies focused on persons who inject drugs, evaluating needle syringe programs in Brazil [35] and in Iran [36]. Nine studies, reporting on seven policies, focused on sex workers. These policies were implemented in Thailand [5, 37, 38], the Philippines [39, 40], China [41], Bangladesh [42], Mexico [43, 44] and the Dominican Republic [6]. The policies evaluated centered on four key themes: outright closure of sex work establishments, registration of sex workers, mandatory clinic visits with health inspections for sex workers, and mandatory condom use in sex work establishments. Two other studies evaluated the inclusion of AIDS education in the weekly curriculum for primary school students in Kenya [45] and modified TB guidelines for use in HIV clinical service to address HIV/TB co-infection in Zambia [4].

Study Design and Quality Assessment

Results of the quality assessment evaluation are presented in Table 2. Most studies included in this review used serial cross-sectional or similar pre/post designs. Seven studies included a comparison group and four included random selection of participants for assessment [6, 37, 43, 46]. Four studies followed a cohort of participants over time [2, 37, 38, 43]. Reflecting the obvious challenges and limitations of evaluating these complex policy interventions, most included studies would be considered as weak in terms of their rigor and

ability to infer causal relationships between the policies implemented and the behavior changes observed.

Policies Addressing Pregnant Women Attending ANC

Four studies evaluated policies focused on pregnant women attending ANCs [2, 3, 32, 33]. In Uganda, PITC was introduced to Uganda's Prevention of Mother-to-Child Transmission (PMTCT) program and new guidelines on the use of antiretroviral (ARV) prophylaxis for PMTCT were issued [2]. Ugandan service providers received a five day training on HIV testing using rapid HIV test kits. They then provided group pre-test group counseling and offered one-to-one post-test counseling to the women attending ANC clinics. In Zimbabwe, PITC was introduced in all ANCs with right of refusal [3]. Clinic counselors held 15-min pre-test group education and discussion sessions with pregnant women; community mobilization activities were implemented to improve public awareness of the PITC policy. In Botswana, PITC was also introduced in ANC clinics, and trained health workers provided group education to all women waiting for their ANC visit [32]. A South African policy revised the clinical guidelines on PMTCT which included initiation of dual zidovudine/nevirapine prophylaxis from 14 weeks' gestation or lifelong antiretroviral treatment (ART) for HIV-positive pregnant women with WHO stage III or IV HIV disease and/or CD4 cell counts below 350 cells/ μ l (Option B+) [33]. During the implementation of South Africa's policy, a nurse quality mentor program provided support to antenatal clinic nurses.

In Uganda and South Africa, a policy was enacted requiring routine HIV testing for all ANC attendees. This policy was associated with significant increases in the number and percentage of women booked for antenatal care visits, counseled for HIV, tested for HIV, identified as HIV-positive, and using antiretroviral therapy for PMTCT [2, 33]. In Uganda, statistically significant increases were found in the number of HIV-positive women delivering in hospitals and in the number of male partners counseled and tested for HIV. A smaller increase in the number of infants given ART for PMTCT was also found [2]. In South Africa, statistically significant decreases in early infant HIV DNA polymerase chain reaction test positivity (at birth and 18-month follow-up) were found following the policy change [33].

The policy interventions in Zimbabwe and Botswana entailed health workers promoting routine HIV testing through group education to ANC attendees [3, 32]. The number and percent of pregnant women tested for HIV and receiving post-test counseling increased significantly in both countries. Zimbabwe's policy intervention also resulted in statistically significant increases in: the number of pregnant women identified as HIV-positive; the number of deliveries by HIV-positive women in antenatal clinics; the number of mother/infant pairs receiving antiretroviral prophylaxis; and in the number of mother/infant pairs attending their 6 week post birth follow up visit at birth clinics. However, the policy had no effect on the number of male partners testing and receiving HIV results [3]. Following Botswana's policy implementation, the percentage of all HIV-positive pregnant women receiving appropriate PMTCT interventions increased from 27 to 80% [32].

People Who Inject Drugs

Two studies evaluated policy interventions targeting PWID with needle syringe programs (NSP), which provide access to clean injection equipment, and other harm reduction services [35, 36]. In Iran, the policy intervention entailed the implementation of NSP in drop-in centers and outreach activities enacted at the city level [36]. In Brazil, the policy intervention established an NSP through a health facility that provided health assistance and referrals for prevention services. This policy was enacted at the city level but was subsequently expanded nation-wide [35]. Both policies established an NSP where PWID could access clean needles, were implemented by health and outreach workers, and were supported by the Ministry of Health of each country. Both policies were associated with significant decreases in syringe sharing among PWID.

In Brazil, other HIV risk behaviors such as unprotected sex decreased as well among PWID accessing NSPs, and syringe cleaning increased over time [35]. These changes took place despite reports of police harassment of PWID and interference with outreach efforts. In Iran, PWID in areas with an NSP reported significantly higher rates of obtaining needles regularly than other injectors in areas without NSPs [36].

Sex Workers

Nine studies evaluated policy interventions for sex workers [5, 6, 37, 39–44]. One additional study presented data on male military conscripts as an evaluation of sex work policies [38]. The types of policies implemented ranged from licensing and registration of sex workers to an outright ban on sex work. Two countries, Thailand and Dominican Republic, implemented 100% condom programs [5, 6]. Though these are characterized by their focus on mandatory condom use, these examples also included mass communication campaigns using television and radio to promote public awareness of high risk sexual practices; provision of an uninterrupted supply of free condoms to commercial sex establishments and to female sex workers; periodic examinations for sexually transmitted infections (STIs); and identification of those commercial sex establishments frequented by men who subsequently sought treatment for STIs, as an unobtrusive measure of non-compliance with the 100% condom policy. Sanctions on non-cooperating brothel owners and managers were also used in some cases.

Four studies examined policies that entailed mandatory enforcement of 100% condom policies among sex workers and clients of sex workers in commercial sex establishments (e.g., brothels, entertainment establishments) [5, 37, 38, 40, 41, 44]. All four studies found that the interventions resulted in significantly higher rates of condom use reported by sex workers after the policy's implementation. Two studies also found significant decreases in STIs among sex workers [5, 6, 37]; one study found significant decreases in STI outcomes among male clients of female sex workers [38]. In the Dominican Republic, the 100% condom policy resulted in significantly higher rates of condom use (with both regular paying and nonpaying partners) and rejection of unsafe sex [6]. In China, knowledge of STIs and HIV, HIV transmission, AIDS, and STI prevention among sex workers in entertainment establishments increased significantly after the implementation of the 100% condom use policy [41]. An evaluation of the 100% condom campaign in Thailand found significantly

reduced behavioral risks (i.e., fewer brothel visits and less inconsistent condom use with female sex workers) and reduced incidence of HIV and STIs among male military conscripts [5, 37, 38].

Two studies reviewed the effect of policies involving registration and routine services for sex workers [39, 43, 44]. In both cases, registration was required for sex workers to acquire government licensing to practice sex work. Continued licensing was contingent upon routine HIV and STI testing at an authorized health clinic. Evaluation of both policies indicated that registered SWs engaged in significantly less unprotected sex than unregistered sex workers. In Mexico, registration among sex workers was associated with higher rates of HIV testing, but not with lower odds of testing positive for any STI or HIV (after adjusting for confounders associated with registration). Registered sex workers engaged in significantly less injection drug use than unregistered sex workers [43, 44].

Combining policy interventions with behavioral interventions was also found to be effective. One study reported that the effectiveness of behavioral intervention for sex workers in the Philippines was enhanced by the existence of a policy [40]. Sex workers who had received behavioral interventions promoting condom use employed in legal entertainment establishments with 100% condom use policy were significantly more likely to report always using condoms compared with establishments in which a 100% condom use policy did not exist.

In Bangladesh, a national effort was made to close all brothels and “rehabilitate” sex workers in six shelter homes [42]. A comparison of surveillance data before and after the national ban revealed a significant increase in the percentage of sex workers with new clients, with 20 or more clients, and with group clients (men who pool their money to hire a sex worker); significant increases in the percentage of sex workers who reported being forced to provide sex services to men in positions of authority, both police and low level political operatives; significant increases in the percentage of sex workers reporting anal intercourse in the last week; and significant decreases in the percentage of sex workers using condoms for any anal/vaginal sex with personal partners in the last week. The ban was opposed by a wide range of actors and rights activists, and eventually repealed.

Primary School Students

One study from Kenya evaluated a national policy that required the teaching of one AIDS lesson a week to upper primary school students in all grades [45]. Questions on HIV and AIDS were also added to national primary school examinations. The policy encouraged behaviors to reduce HIV infection and included activities to build self-efficacy for abstinence. It was implemented nation-wide and was enforced by government officials and schools.

The evaluation of this education policy measured three outcomes: HIV knowledge, normative support for condoms, and self-efficacy for abstinence. At 18 months, mean HIV knowledge scores and the percentage of students (boys and girls) scoring more than 50% on the HIV knowledge test had decreased from the baseline assessment; at 30 months, however, this result was significantly reversed. Evidence of increased normative support for condom

use was found at the 30-month follow-up assessment; no increase in normative support was found in prior assessments. Self-efficacy for abstinence, on the other hand, increased significantly among both boys and girls at both the 18- and 30-month follow-ups.

Among students who reported sexual experience, the likelihood of engaging in sex in the last three months decreased at 18 months for both boys and girls. For girls, the likelihood of sexual debut decreased significantly from baseline to 18 months and the likelihood of condom use at last sex increased from 18 months to 30 months. Resistance to condom instruction from teachers was reported as a significant barrier to the policy's implementation.

Patients with Tuberculosis Attending Health Care Clinics

One study evaluated routine PITC for patients with TB attending health care clinics [4]. This policy was implemented and enforced by trained health workers on a national level and encouraged enrollment in HIV care and treatment services. After the policy's implementation, 69% of TB patients tested for HIV were identified as HIV-positive. Of these, 88% were eligible for immediate ART initiation. As a result, the proportion of TB patients accessing HIV care and treatment increased significantly.

Discussion

This systematic review identified strong evidence that HIV prevention policies implemented among multiple populations in many low- and middle-income country settings can effectively change HIV-related behaviors. However, despite the attention that policy interventions have received since the HIV epidemic began, we identified only a limited set of studies that implemented policies and evaluated the outcome. Therefore, the first key finding of this review is that more evaluation of policy interventions, carried out with more rigor, are needed. Though many of these policy interventions were primarily local or national efforts, some clearly relied on international donor support. Donors and development agencies need to be more insistent on the inclusion of rigorous evaluations capable of detecting the effects of these efforts.

All fifteen policies included in this review demonstrated at least some statistically significant changes in HIV-related outcomes, though some were negative and clearly not anticipated [42]. Others, like a fourfold increase in condom use among sex workers with new clients [6] or in pregnant women accepting HIV testing in prenatal care [2], clearly suggest the potential of interventions promulgated through policies. Because most policies were implemented on a national level, the effects were potentially more broadly distributed than may be the case with individually focused interventions or with interventions that are implemented on a regional or local basis. For example, before the 100% condom use program in Thailand became a national policy, some men tried to find sex work establishments where condom use was not enforced, which led to poor HIV-related outcomes as well as poor business outcomes for sex work establishments that were voluntarily enforcing the 100% condom use policy [5, 37].

We identified no studies meeting our eligibility criteria that examined HIV policy interventions among populations such as men who have sex with men, adult females not

employed in sex work, or sero-discordant couples, and only a limited number of studies with other important populations, such as patients with TB, primary school students, and PWID. Policy interventions implemented subsequently with these populations should be rigorously evaluated to add to the existing evidence available.

The failure of well-intentioned policy initiatives to improve the problem they were meant to address or even to cause the opposite reaction, sometimes called the “cobra effect” [47] has attracted attention in behavioral economics and has been documented in the historical literature [48]. This effect can explain some of the unanticipated outcomes that were seen with the larger policy changes reviewed. One possible lesson from this review may be that small incremental policy changes are more productive and less susceptible to unforeseen consequences than larger policy changes. Another lesson may be that, in general, policies that “nudge” people toward desirable reduced risk options or behaviors [9] may be preferable to policies that attempt to prohibit or block behaviors. Encouraging healthy options, such as changes in clinical policies from “opt in” to “opt out” HIV testing, led to increased acceptance of healthy options and opportunities for HIV prevention. Efforts to block riskier behavioral options, like the 100% condom policy in Thailand, were sometimes effective in the short term but with diminishing effects over time, as the nature of sex work adapted to the new restrictions [46]. The adverse outcome was even greater in Bangladesh where a misguided policy effort drove sex work underground and out of the reach of public health [42] and suggests a further lesson: the reach possible with large-scale policy interventions is a marked advantage when the policy is well considered. When it is poorly considered, however, the unintended consequences can be broad, and counterproductive, as well.

Decision-makers should ensure that all policy interventions affirmatively protect human rights, especially for marginalized populations that often lack the power to protect themselves. Some policies included in this review resulted in serious human rights violations [e.g. 42]. Two other policy interventions required sex workers to be tested for HIV and STIs in order to retain their right to work. Depending on how they are implemented, such policies may violate human rights and, if they encourage sex workers to operate outside the law they may have limited or even negative public health benefit. Additionally, these policies, designed to maintain or improve public health, are often enforced by the legal system that is tasked with maintaining public order, resulting in conflict. For example, although the Ministry of Justice's Federal Council on Psychoactive Drugs approved NSPs in Brazil, police brutality of NSP outreach workers and PWID obtaining legal harm reduction services created significant barriers to the policy intervention's implementation [36]. Balancing public health goals with law enforcement interests may be one challenge to using policy to achieve public health goals while respecting the need for public order.

Though the reach can be broad, policy implemented on a national level may fit poorly into a local social context. For example, the mandatory registration of sex workers in Mexico required registrants to pay \$360 for an annual registration card and mandated they receive monthly testing for HIV and quarterly STI screening to work legally [43, 44]. This was a significant financial burden on poorer women and especially street-based and drug-using sex

workers at greatest risk of HIV and STIs and may have resulted in less prevention effectiveness among them.

It is important to acknowledge that most of the policy interventions included in this review were supplemented with behavioral interventions, education interventions, and/ or community mobilization activities. In fact, the purpose of many of these policy interventions was to lower barriers to access these other interventions. Many of these were multi-component interventions of proven effectiveness in preventing HIV. As a consequence, some may argue that it was the effect of these other interventions that was seen in these policy evaluations. However, these interventions were still effective overall in facilitating the uptake and use of the behavioral interventions that were part of the policy effort. In fact, the evidence suggests that combining behavioral interventions with policy interventions can be more effective than a behavioral intervention alone, as the experience from the Philippines has shown [40]. This finding lends some support to the position that policy interventions may be more effective than individual level interventions, or at least be an important complement.

While this systematic review was carefully conducted, it is not without limitations. Reported outcomes should be interpreted with caution as most studies included in this review relied on self-reported outcomes, which are vulnerable to bias, and on short assessment periods that may fail to capture longer-term effects. Furthermore, most studies included in this review used research designs that are incapable of clearly and unequivocally establishing cause of HIV-related behavior outcomes. Future studies evaluating HIV policy prevention interventions in low-and middle-income countries should consider study designs that enable monitoring of HIV-related behaviors before, during, and after the policy's intervention with a comparison group and for longer periods of time. Close attention should be paid to historical and contextual events to better assess the effect of the policy on HIV-related behavioral outcomes.

Despite the limitations highlighted above, however, this systematic review suggests that some types of HIV prevention policy interventions in low-and middle-income countries can be an effective strategy to change HIV-related behaviors. In an environment of decreasing resources for HIV programmes overall, well-designed policy interventions, developed and assessed at a local level before national level implementation, can be an attractive strategy for increasing the effectiveness of HIV programme efforts for prevention, treatment and care.

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Fig. 1. Flow chart depicting disposition of study citations

Table 1
Study description table

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
Andrade et al. [35]	Brazil Salvador, state of Bahia	<p>People who inject drugs (PWID) in Salvador</p> <p><i>Gender</i> Before NEP Pelourinho: 81.9% male 18.1% female After NEP: Engenho Velho 91.9% male 8.1% female <i>Age</i> Before intervention Pelourinho: <i>Mean</i> 25.2 years <i>After intervention Engenho Velho mean</i> 24.6 years</p>	<p><i>Policy intervention</i> The Ministry of Justice's Federal Council on Psychoactive Drugs approved Needle Exchange Programs (NEPs) associated with research programs</p> <p><i>Study intervention</i> 11 staff members, including one doctor, two nurses, two social workers, and one psychologist trained in HIV Prevention specifically for PWID provided harm reduction services to PWID within Sao Francisco Health Service facility. Services included health assistance and referrals, as well as HIV prevention strategies including syringe exchange and condom distribution</p>	<p>Serial cross-sectional study design</p> <p>Assessments took place before NEPs were fully in place in the Pelourinho, Salvador between July 1994 to September 2006 (N = 221) and after the NEPs were in place in the Engenho Velho, Salvador between March-September 1997 (N = 62). Participants were non-randomly selected</p>
Byamugisha et al. [2]	Uganda District of Mbale, Eastern Uganda	New female ANC attendees and male-partners accessing antenatal care (ANC) in Sub-Saharan Africa	<p><i>Policy intervention</i> In concordance with CDC and UNAIDS/WHO recommendations, routine HIV counseling and testing (RCT) was introduced to Uganda's PMTCT program and the following new guidelines on the use of antiretroviral (ARV) prophylaxis from PMTCT was issued: immediate Zidovudine (AZT, ZDV) 300 mg, Lamivudine (3TC) 150 mg twice a day starting at 32 weeks gestation and continued through out labor, and a single dose NVP 200 mg booster shot at the onset of labor. Post labor, the women are required to continue with AZT plus 3TC twice a day for one week. The baby receives a single dose of NVP syrup within</p>	Retrospective cohort study design

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
Chandisarewa et al. [3]	Zimbabwe Chitungwiza, Harar	Pregnant women receiving ANC in Zimbabwe <i>Gender</i> 100% female <i>Age</i> NR	<i>Policy intervention</i> PITC with right of refusal was offered to all new ANC clients during ANC visits <i>Study intervention</i> Community mobilization activities for improving public awareness of the routine HIV testing policy were carried out by community outreach counselors. Prevention of Mother to Child Transmission (PMTCT) clinic counselors held 15-minute group education and discussion sessions with pregnant women, using a structured flip chart as a discussion guide. The discussion focused on HIV transmission, PMTCT, sdNVP prophylaxis and routine HIV testing for all mothers, specifying the right to refuse	for the 1991 cohort, N = 1292 for the 1993 cohort), and 24 months (N = 1795 for the 1991 cohort, N = 672 for the 1993 cohort). Participants were non-randomly selected into the study Serial cross-sectional study design Assessments took place for a 6-month period in 2004–2005 during opt-in testing (N = 4872) and for a subsequent 6-month period in 2005 during opt-out testing (N = 4551). Participants were non-randomly selected
Creek et al. [32]	Botswana Francistown	Pregnant women in Botswana seeking ANC <i>Gender</i> 100% female <i>Age</i> Mean during Routine Testing: 22.5 years <i>Mean during voluntary testing</i> 22.5 years	<i>Policy intervention</i> Botswana's President Festus Mogae published a New Year message to the nation, stating that starting 2004, HIV testing in health care facilities would be "routine but not compulsory" and that "healthcare workers will test for HIV unless you decline to be tested" <i>Study intervention</i> Trained health workers provided group education (i.e. sessions on HIV transmission, PMTCT, and ARV therapy; a brief explanation of all tests done during ANC [hemoglobin, syphilis, HIV, glucose, and blood pressure], and a	Serial cross sectional study design Assessments took place at four clinics during voluntary HIV testing period (N = 492) and 8-months later, after the routine HIV testing policy was instituted (N = 964). Participants were non-randomly selected

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
			Health developed and adopted guidelines for screening, diagnosis, and treatment of TB in HIV/ AIDS services based on recommendation from the WHO's Interim Policy on Collaborative TB-HIV Activities. National TB treatment cards were modified to include HIV-related information. TB-HIV coordinating teams were formed to include key partners from government, international agencies, and nongovernment organizations	
		Gender NR Age NR	<i>Study intervention</i> Group education sessions in the waiting area of the TB department provided information on TB-HIV co-infection, medical benefits of knowing one's HIV status, and the importance of HIV prevention	Assessments took place at baseline during the 3 months prior to the policy integration (N = 2137), and during the 3 months following the policy intervention (N = 2343). Participants were non-randomly selected
Jenkins et al. [42]	Bangladesh	Female SWs living in nationally registered brothels in Bangladesh	<i>Policy intervention</i> The Social Welfare State Minister announced all brothels would be forcibly closed and SWs would be rehabilitated in six shelter homes	Serial cross-sectional study design
		Gender 100% female Age Mean: 22.1 years Range: 12–45 years	<i>Study intervention</i> Activities of non-governmental organizations classified as educational (e.g., HIV prevention), educational plus STD clinic services, and none	Assessments took place at baseline (N = 1147) and 24 months post-intervention (N = 867). Participants were randomly selected
Kerrigan et al. [6]	Dominican Republic Puerto Plata	SWs and sex worker establishments in Puerto Plata	<i>Policy intervention</i> Regional governmental policy requiring condom use between SWs and clients in sex establishments	Serial cross-sectional study design
		Gender 100% female Age 54% were between 18 years and 25 years	<i>Study intervention</i> The intervention included 4 other components: (1) Solidarity and	Assessments took place at baseline (N = 200) and at 12 months (N = 200) post-intervention. Participants were randomly selected

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
		46% were older than 26 years	collective commitment—quarterly workshops, monthly follow-up meetings and educational materials. (2) Environmental cues—100% condom posters, glass bowls filled with condoms, stock of condoms at all times, disc jockey messages, information booths, educational materials and interactive theater presentations. (3) Clinical services—trained clinicians and government health inspectors on basic HIV/AIDS information, data collection and monitoring and ethical procedures. Sex worker peer educators provided pretest–posttest STI counseling. (4) Monitoring and encouraging adherence. Owners of the sex establishments met with NGO staff and regional public health officials quarterly to discuss barriers to implementation, with non-adherers subject to a graduated sanction system	
Liu et al. [39]	Philippines Iloilo City	SWs in the Philippines during the 1990s	<i>Policy intervention</i> Policy required sex establishments to obtain licenses, and “hospitality girls” working in licensed establishments were required to register with the local authority. Registered “hospitality girls” were issued work permits that had to be renewed on a weekly basis by visiting the local Social Hygiene Clinic and getting tested for STDs. Tests for HIV and syphilis were given semiannually	Multi-arm cross-sectional study design
		<i>Gender</i> 100% female <i>Age</i> Mean of <i>Registered SWs</i> 23 years	<i>Study intervention</i> No additional study intervention was implemented	Assessments took place at baseline (N = 110 for registered SWs and N = 46 for freelance SWs). No follow-up. Participants were non-randomly selected

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
Maticka-Tyndale et al. [45]	Kenya Nyanza Province	Mean of Freelance CSWs: 21		
		Upper-primary pupils in Standards 6 and 7 in Kenya	<i>Policy intervention</i> Kenya's Ministry of Education mandated the teaching of one AIDS lesson a week in all grades. Questions on HIV and AIDS were added to national primary school examinations	A serial cross-sectional study design
		<i>Gender</i> 56% male 44% female <i>Age</i> Range: 11–17 years Mean: 14.1 years	<i>Study intervention</i> The intervention entailed the Primary School Action for Better Health Program, which was a teacher training to mobilize the HIV curriculum. The curriculum content included skills for resisting pressures to engage in sexual intercourse, combating stigmatization related to HIV, and caring for people with AIDS. During the second year of the program, local health workers provided support in informing youth about sexuality and condoms	Assessments took place at baseline (N = 953) and at 18 months (N = 1119) and 30 months (N = 1340) post-intervention. Schools of participants were randomly selected
Morisky et al. [40]	Philippines Southern Luzon, Cebu, Ilo-Ilo, and northern Mindanao islands	SWs in the Philippines	<i>Policy intervention</i> Mandatory 100% condom use policy within sex establishments	Cross-sectional study design
		<i>Gender</i> 1.4% male 98.6% female <i>Age</i> Range: 15–54 years Mean: 23.5 years	<i>Study intervention</i> No additional intervention was implemented; however, this policy was added to the “educational policy” (i.e., the promotion of AIDS awareness, the provision AIDS education for workers and educational materials to customers, and the reinforcement of SWs' [unspecified] positive behaviors), and mandated weekly and bimonthly social hygiene clinic visits for SWs that were pre-existing within sex establishment sector	Assessments took place at baseline (N = 769). Participants were non-randomly selected

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
Rojanapithayakorn et al. [5]	Thailand	SWs and their clients at commercial sex establishments	<i>Policy intervention</i> Thailand's National AIDS Committee implemented the 100% condom program policy. The 100% condom program policy entailed: (1) Mass communication campaign using television and radio to promote public awareness of high risk sexual practices; (2) Providing a continuous supply of free condoms to commercial sex establishments and to female sex workers (SWs) during periodic STD examinations; and (3) Commercial sex establishments used by men treated for STDs were identified and targeted to enforce the establishment's compliance with the program's condom recommendations	Cross sectional post-hoc evaluation of the 100% condom program
		<i>Gender</i> NR <i>Age</i> NR	<i>Study intervention</i> No additional study intervention was implemented	Selection of participants could not be coded
Sakhondavat et al. [37]	Thailand Khon Kaen City	SWs and brothel managers in Thailand	<i>Policy intervention</i> The proposed AIDS law (i.e., 100% condom use program) being considered by Thailand's Parliament	Time series study design
		<i>Gender</i> NR <i>Age</i> SWs age mean: 21.7 year SWs age range: 14–33	<i>Study intervention</i> The brothel managers ('mamasans') viewed a presentation of AIDS, which provided basic information on HIV infection and prevention, and were introduced the content of the 100% condom use program, and its expected impact on HIV/AIDS. The mamasans were all given a token supply of condoms and were followed-up once per month for condom resupply and reinforcement in pursuing the condom-only policy.	Assessments took place at baseline (Brothels N = 24, SWs N = 217) and at 6 monthly follow ups (<i>Month 1</i> Brothels N = 19, SWs N = NR, <i>Month 2</i> Brothels N = 19, SWs N = NR, <i>Month 3</i> Brothels N = 16, SWs N = 109, <i>Month 4</i> Brothels N = 14, SWs N = NR, <i>Month 5</i> Brothels N = 18, SWs N = NR, <i>Month 6</i> Brothels N = 16, SWs N = 88). Participants were non-randomly selected
Sirotn et al. [43]	Mexico Tijuana	Female SWs	<i>Policy intervention</i> Government regulation system	Prospective cohort study design

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
			<p>entailed voluntary registration of SWs with the municipal health department (MHD). Registrants must pay \$360 for an annual registration card, and are fined if they are unregistered. Registrants are required to receive monthly testing for HIV and quarterly STI screening to legally work. If they test positive for an STI, they are treated with antibiotics according to federal STI guidelines and their registration card is temporarily held until the MHD cleared them. If registrants are found to be HIV-positive, their registration cards are revoked, and they are referred to specialty care.</p> <p><i>Study intervention</i> The behavioral intervention, <i>Mujer Segura</i>, which employed motivational interviewing and social cognitive theory to promote condom negotiation skills among SWs</p>	<p>Assessment took place at baseline (N = 187) and at a 6-month follow-up (N = 187). Participants were non-randomly selected</p>
Sirotin et al. [44]	Mexico Tijuana	<p>Female SWs</p> <p><i>Gender</i> 100% female <i>Age</i> Median: 32 years Age range: 26–40 (IQR)</p>	<p><i>Policy intervention</i> Government regulation system entailed voluntary registration of SWs with the municipal health department (MHD). Registrants must pay \$360 for an annual registration card, and are fined if they are unregistered. Registrants are required to receive monthly testing for HIV and quarterly STI screening to legally work. If they test positive for an STI, they are treated with antibiotics according to federal STI guidelines and their registration card is temporarily held until the MHD cleared them. If registrants are found to be HIV-positive,</p>	Cross-sectional study design

Study	Setting	Population characteristics	Policy intervention & study intervention descriptions	Study design
			their registration cards are revoked, and they are referred to specialty care	
		<i>Gender</i> 100% Female <i>Age</i> Median: 32 years	<i>Study intervention</i> No additional study intervention was implemented	Assessments took place at one time point (N = 419). Participants were non-randomly selected, but locations units were randomly selected
Zamani et al. [36]	Islamic Republic of Iran Tehran	Active PWID in Tehran	<i>Policy intervention</i> Iran health policy makers adopted a harm reduction drug policy, which entailed a needle syringe program (NSP)	Cross-sectional study design
		<i>Gender</i> 100% male 0% female <i>Age</i> Mean in intervention group: 30.8 years Mean in control group: 33.1 years	<i>Study intervention</i> NGOs implemented the NSPs through drop-in centers and outreach activities	Assessments took place at one time point (N = 419). Participants were non-randomly selected, but locations units were randomly selected
Zhongdan et al. [41]	China Wuhan	Female SWs who work at entertainment establishments in Wuhan, China	<i>Policy intervention</i> The 100% Condom Use policy mandated that all entertainment establishments (EEs) require condom use in all commercial sex encounters.	Serial cross sectional study design
		<i>Gender</i> 0% male 100% female <i>Age</i> Mean: 20.3 years Range: 15–31 years	<i>Study intervention</i> Additional individual level strategies were applied, which included discussion with SWs focused on knowledge, attitudes, and behavior related to HIV/STI transmission. Community-level strategies sought to inform various leaders, interested groups, and the general public of the project objectives, and also change community norms. Owners of EEs were asked to have condoms readily available for CSWs. Finally, in order to reach as many SWs as possible, seven 1-day training workshops were held over several months about the policy, AIDS/STI-related knowledge, condom use, and client persuasion	Assessments took place at baseline (N = 170), 6-months (N = NR), 9-months (N = NR), 12-months (N = NR), 15-months (N = NR), and at 21-months (N = 102) post-intervention. Participants were non-randomly selected

Table 2

Study quality assessment

Study	Cohort	Control or comparison group	Pre/post intervention data	Random assignment of participants to the intervention	Random selection of participants for assessment	Follow-up rate of 80% or more	Comparison groups equivalent on socio-demographics	Comparison groups equivalent at baseline on outcome measure
Andrade et al. [35]	No	No	Yes	No	No	NA ^a	NA	NA
Byamugisha et al. [2]	Yes	Yes	Yes	No	No	No	No	NR ^b
Celentano et al. [38]	Yes	No	Yes	NA	No	NA	NA	NA
Chandisarewa et al. [3]	No	Yes	Yes	NA	NA	NR	NR	NR
Creek et al. [32]	No	No	Yes	No	No	NA	NA	NA
Grimwood et al. [33]	No	No	Yes	NA	No	NA	NA	NA
Harris et al. [4]	No	No	Yes	NA	No	NA	NR	NR
Jenkins et al. [42]	No	No	Yes	NA	Yes	NA	NA	NA
Kerrigan et al. [6]	No	No	Yes	No	Yes	NA	NA	NA
Liu et al. [39]	No	Yes	No	NA	No	NA	No	NA
Maticka-Tyndale et al. [45]	No	No	Yes	No	Yes	NA	NA	NA
Morisky et al. [40]	No	Yes	No	NA	No	NA	NA	NA
Rojanapithayakorn et al. [5]	No	No	Yes	NA	No	NA	NA	NA
Sakhondavat et al. [37]	Yes ^c	No	Yes	NA	NA	No	NA	NA
Sirotnin et al. [43]	Yes	Yes	No	No	No	Yes	No	No
Sirotnin et al. [44]	No	Yes	No	No	No	No	No	No
Zamani et al. [36]	No	Yes	No	NA	Yes	NA	No	NA
Zhongdan et al. [41]	No	No	Yes	NA	No	NA	NA	NA

^aNA indicates that the specific rigor criterion was not applicable to the study design assessed

^bNR indicates that the specific rigor criterion was not reported by the authors

^cAuthors followed a cohort of brothels from baseline to a 6-month follow-up; however, they surveyed a different sample of SWs at baseline, the 3-month follow-up, and the 6-month follow-up