



Editorial

Evaluation of HIV prevention interventions for people who inject drugs in low- and middle-income countries—The current and future state of the art

Inter-related epidemics of HIV and injection drug use occur globally but are especially prevalent and expanding in low- and middle-income countries (LMIC) (Bergstrom & Abdul-Quader, 2010; Beyrer et al., 2010; Mathers et al., 2008). Harm reduction interventions have long been deployed to prevent HIV infection and Alex Wodak, a leading advocate, has declared the scientific debate on their effectiveness to be over (Wodak, 2006, 2008). Perhaps the debate should be over after three decades of evaluation and the accumulation of a wealth of evidence but, in many countries, including LMIC, debate and opposition to harm reduction persist, much of it driven by ideology and politics, shortages of resources, lack of political will, and continuing stigmatization of people who use drugs (Des Jarlais et al., 2013). In some countries, assertions regarding lack of evaluation simply mask deeper opposition that no data will be able to overcome. Requirements for repeated “pilot tests” have also been used to delay scale-up of harm reduction interventions.

As a result of all of these factors, uptake and coverage of harm reduction interventions in LMIC remain at low levels. There is a continuing need for better evidence and more effective mobilization of that evidence to achieve improvements in policy and practice.

Current state of the art

In 2007, the Institute of Medicine (IOM) conducted an extensive review of the evidence on peer education, needle/syringe programmes (NSP), and opioid substitution treatment (OST) in countries with injection-driven HIV epidemics. It concluded that peer education and NSP were effective in reducing HIV risk behaviours as part of multi-component programmes but that evidence linking these interventions to reduced HIV incidence was inconclusive. Only OST was found to have a stand-alone positive effect (Institute of Medicine, 2007). Another review concluded that OST was effective in reducing addiction severity and improving quality of life (Feelemyer, Des Jarlais, Arasteh, Phillips, & Hagan, 2014). Psychosocial interventions have received positive reviews, albeit acknowledging that downward trends in risk behaviours were typically identified in both intervention and comparison groups (Meader, Li, Des Jarlais, & Pilling, 2010). By contrast, Des Jarlais and Semaan (2005) concluded that interventions designed to reduce sexual risk behaviours among PWID were not demonstrably effective, which highlights a common weakness in HIV prevention programmes for PWID.

The evaluation gaps remain the same as they were at the time of the 2007 IOM assessment. A recent review of evaluation

designs (Hammett & Parsons, 2014) found that the most common are based on process data and pre-post comparisons of risk behaviours. There have been some ecological studies of coincident interventions and epidemiologic and behavioural trends. Major gaps remain in rigorous outcome evaluations employing biological measures and appropriate comparisons, such as in randomized controlled trials and quasi-experiments, as well as disaggregation of the effects of the elements of combination prevention (WHO, UNAIDS and UNODC, 2009, 2012). There have been a small number of cost-effectiveness studies but no assessments considering the relationships between interventions and larger health systems.

Process monitoring, the most common form of “evaluation”, cannot determine whether an intervention was successful in achieving all of its objectives but only whether it was successfully implemented. The frequency of such assessments results in part from major donors such as PEPFAR, Global Fund, and World Bank requiring primarily reports of process data rather than outcome data. Process monitoring typically tabulates the number of individuals reached, the volume of services provided, or the quantity of commodities distributed with coverage measured in terms of geography or population. The emergence of implementation science may presage more sophisticated and outcome-oriented analysis employing process data to understand the barriers and facilitators of achieving desired outcomes of interventions (Schackman, 2010).

Other important dimensions of process assessment are the structures and factors comprising the context for interventions. A few analyses have examined the roles of ideology, politics, and laws and policies (e.g. Edington & Bayer, 2012; Hammett et al., 2008), and relationships with government sectors such as police (e.g. Hammett et al., 2005; Jardine, Crofts, Monaghan, & Morrow, 2012; Sharma & Chatterjee, 2012) and non-governmental stakeholders such as civil society organisations (e.g. Narayanan, Vicknasingham, & Robson, 2011).

By far the most common form of *outcome/impact evaluation* compares pre-post observations of risk behaviours using cohort or cross-sectional data. Far fewer evaluations employ biological outcomes such as HIV prevalence and incidence, which are more objective than behavioural measures, which are normally self-reported and thus subject to biases. All observational studies limit the inferences of causation that may be drawn between interventions and observed outcomes. Moreover, since most evaluations are of short duration, they are unable to measure the durability of intervention effects. An exception is the evaluation of the Cross-Border project in Vietnam and China that reported positive trends in behaviours, HIV prevalence, and HIV incidence over

eight years of implementation of a peer-based NSP (Hammett et al., 2012). This was the first evaluation of an HIV prevention intervention for PWID in a LMIC that used HIV incidence as an outcome.

Prevalence trends may be affected by factors apart from the intervention such as death rates, mobility, instability or other changes in the target population forming the denominator. Still, major downward trends in prevalence probably reflect at least some reduction in incidence. HIV incidence is the most robust outcome measure but it also poses challenges. Tests for recent infection, especially the BED assay, which have been used to estimate incidence from cross-sectional data, may give false-recent results for individuals on ARV treatment or with long-term HIV infection (Marinda et al., 2010; Welte, McWalter, Laeyendecker, & Hallett, 2010). Adjustment factors have been used to correct for false recent BED test results in incidence estimation (Welte, McWalter, & Barnighausen, 2009) and newer tests for recent HIV infection, such as the LAG-avidity assay, show promise of reducing false-recent results. Work is also underway to develop new methods for identifying recent HIV infection (Incidence Assay Critical Path Working Group, 2011), including multi-assay algorithms (Laeyendecker et al., 2013) and automated point-of-care readings of multiple analytes (Pilcher et al., 2012).

Ecological studies analyse coexisting aggregate phenomena and attempt to draw connections between them based on overwhelmingly consistent evidence. Large ecological reviews (Hurley, Jolley, & Kaldor, 1997; MacDonald, Law, Kaldor, Hales, & Dore, 2003) covering both developed countries and LMIC revealed much more pronounced downward trends in HIV prevalence among PWID in cities with NSPs than those without such programmes.

Quasi-experimental designs involve non-randomized comparisons between sites or groups of individuals receiving different levels of intervention but otherwise as similar as possible demographically, socio-economically and along other key dimensions. There have been very few quasi-experimental evaluations of HIV prevention interventions for PWID in LMIC (e.g. Booth et al., 2011; Zamani et al., 2010; Zhou et al., 2009).

Randomized controlled trials (RCT) represent the gold standard for evaluation of interventions. RCTs to evaluate HIV prevention interventions for PWID in LMIC are very rare (e.g. Go et al., 2013; Metzger et al., 2012; Schottenfeld, Chawarski, & Mazlan, 2008), with cost, lack of local capacity, and ethical considerations as the primary barriers. RCTs are very expensive and, particularly in LMIC, such expenditure might be considered inappropriate diversion of resources from vital services. Moreover, it is in most cases ethically unacceptable to withhold services for research purposes.

Cost-benefit and cost-effectiveness analyses of harm reduction interventions in LMIC are also uncommon (e.g. Khan & Khan, 2011; Li, Gilmour, Zhang, Koyanagi, & Shibuya, 2012; Ni, Fu, Chen, Hu, & Wheeler, 2012). A limited number of donor-driven interventions have attempted to strengthen HIV prevention programmes for PWID using a health systems approach (Quality Health Project, 2011) but no evaluations have examined how health systems affect prevention of HIV among PWID, or, conversely, how HIV among PWID affects health systems.

Recommendations for the future

Based on our review of evaluation methods and evidence and our understanding of the contexts in which evaluation evidence must be deployed to promote improved HIV prevention programmes for PWID in LMIC, we offer some recommendations to fill the gaps in evaluation, advance the state of the art, enhance the evidence, and improve policy advocacy in settings where resources may be increasingly constrained.

- *Design evaluations based on the political and ideological context.* Evaluation should be both policy-driven and method-driven. Evaluators and funders should consider the amount of further evaluation needed to achieve desired policy and programmatic goals in light of available funding and resources. The extent to which governments are willing to accept international as opposed to domestic data for decision-making should also be considered.
- Although local contexts vary, in general, there is a *need for more rigorous evaluation* with the focus shifting from process measures to outcomes, as strongly recommended in the Institute of Medicine's evaluation of PEPFAR (Institute of Medicine, 2013). The U.S. Agency for International Development and the U.K.'s Department for International Development have both recently increased their emphasis on rigorous evaluation of the programs they support and all funders should follow this lead.
- Particularly in resource constrained settings, funders and evaluators should *weigh the costs of evaluation against the possible benefits in terms of improved HIV prevention programmes*. Whenever possible, evaluations should use the least expensive data, the smallest sample sizes, the shortest follow up periods, and the fewest comparisons needed to measure results with acceptable precision. The availability of better surveillance data would facilitate use of less expensive observational and ecological evaluation designs and development of better estimates of intervention coverage (Mathers, Cook, & Degenhardt, 2010; Mathers et al., 2010).
- Since HIV prevention programmes for drug users rarely involve only one intervention, it is important to *devise better methods to evaluate combination prevention* in order to understand better the relative effectiveness of components both singly and in combination (Degenhardt et al., 2010). A small number of cost-effectiveness investigations have used compartmental modeling for costing intervention components (Alistar, Owens, & Brandeau, 2011; Li et al., 2012) and combinations of interventions (Dutta et al., 2013). Such information could inform better programme decision making in resource-constrained settings where international donors are cutting their support.
- *Evaluate the relationships between HIV prevention interventions and health systems* to increase understanding of the effects of HIV infection and HIV prevention interventions on systems and, conversely, the effects of integrated services and other health system enhancements on the funding, implementation, and outcomes of interventions. Consideration of these system dimensions and the potential for improving cost-efficiency are also particularly important in countries with limited resources and reduced donor support.
- In investigating causation, analysis of evaluation data should *consider the effects of natural epidemic progression, demographic changes, and programmatic factors*. HIV epidemics driven by injection drug use may naturally plateau or decline regardless of the presence or absence of interventions. De Vos, van der Helm, Matser, Prins, and Kretzschmar (2013) concluded that observed reductions in HIV and HCV incidence in Amsterdam were as much the result of naturally occurring changes in the IDU population as of the city's long-standing harm reduction programmes but a commentary on this paper emphasized the complex challenges in disentangling multiple causal factors (Vickerman & Hickman, 2013).

Several studies in Vancouver and Montreal in the 1990s suggested that attendance at NSPs was associated with higher risk of HIV infection among PWID, findings that fuelled opposition to NSP. However, subsequent investigation revealed that this association resulted from the extremely high-risk population drawn to the NSP and service deficiencies of the programmes (Bastos & Strathdee, 2000).

• Evaluations should include plans to use the evidence to advocate for improvements in laws, policies, and programmes. Experience amply demonstrates that evidence, no matter how compelling, often cannot by itself achieve desired changes. This does not remove the need to continue improving evaluations and evidence but it does underline the concurrent need for attention to advocacy as well as sound science. Evaluators and advocates should design studies to produce the types of evidence that are most likely to influence decision makers. In some cases, this may be evidence of infections averted, cost effectiveness, and cost savings. Strong evidence that harm reduction interventions do not increase the prevalence or severity of drug use or other negative outcomes may also be useful. In every setting with strong political or ideological opposition to harm reduction, careful assessment of the types of evidence most likely to counteract this opposition should drive the design of evaluations and analyses of data.

Despite three decades of accumulating evidence, harm reduction interventions for HIV prevention among PWID remain under-utilized, particularly in LMIC. “Getting to Zero” new infections among PWID will require not only better and more compelling evidence to end, finally and completely, the scientific debate on harm reduction but also the more effective deployment of that evidence to advocate for and achieve universal adoption of harm reduction interventions.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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