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Coverage of HIV prevention programmes for injection drug users: confusions, aspirations, definitions and ways forward.

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The concept of coverage first emerged in the 1960s as a key indicator for measuring the proportion of populations that were covered by health care, particularly with respect to communicable diseases and immunization programmes. WHO has defined the term in a manner that intrinsically links effectiveness with coverage – 'the proportion of the population in need of an intervention which has received an effective intervention' (Hogarth, 1975;WHO, 2001). The concept of coverage received particular attention in the early 'Health for All' era related to the Alma Ata Declaration of 1978 (WHO, 2001). The 1980s and 1990s saw a rising concern with access, utilisation and equity - which dimmed the focus on achieving targets related to coverage.

As a concept, 'coverage' has become rapidly absorbed into HIV prevention discourses, and the term has become frequently used in both academic and programme related literature. In the 1990s and early this century, there have been increasing calls for 'high-coverage' interventions. In this sense, 'coverage' has became inspirational – a call to action and a spur to move beyond small scale demonstration projects. Achieving 'high coverage' has become something that all 'good' interventions aspire to, and the cost of failing to achieve 'high coverage' has been documented across the world from Nepal to Madrid (Peak et al, 1995; Feunte et al, 2006). This inspirational aspect of coverage has perhaps not always been balanced adequately with the theoretical robustness of a concept emerging from communicable disease control and applied to a largely behavioural disease, which is deeply influenced by structural and contextual factors. That is, very little research has empirically linked levels of coverage to HIV spread among IDUs prospectively; the parameters of coverage required to reach "herd immunity" (Anderson and May 1990;Nokes and Anderson 1988) remain largely unknown

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although at least one team of investigators have begun to address this issue using mathematical modeling techniques (Vickerman et al 2006)

The importance of coverage is emphasized in the Universal Access approach recently adopted by WHO, UNAIDS and its other partner organizations, which has led to calls for more consistent methods of measuring and comparing coverage rates of HIV interventions. 'Coverage' is now also used increasingly in the context of HIV prevention programmes among injecting drug users (IDUs), including needle syringe programmes (NSPs), outreach, and opioid substitution programmes such as methadone maintenance treatment. In the Universal Access era, this has meant a renewed interest in coverage estimation methods and coverage targets with both UNODC and WHO (in mid 2006) working on methods to assist countries in meeting HIV prevention coverage targets related to injecting drug users (personal communications: Dr Christian Kroll, UNODC; Dr Annette Verster, WHO).

However, a great deal of confusion remains around the concept of coverage as it is applied to HIV prevention programmes among IDUs. Arguably, the introduction of a concept, without also assisting users to understand its dimensions, its "demands", the critical necessary conditions which are necessary for it to operate (or not to operate) and whether its underpinnings are theory-driven, empirically-based, or based upon "principles of faith", simply ensures that the term remains a shibboleth in a field of many stereotypes.

This paper is an attempt to examine some of the meanings of coverage of HIV prevention programmes among IDUs and how these meanings differ within and between settings. It is based on a review of the HIV prevention and care literature and on a set of papers provided to a Satellite Session of the 17th International Conference on the Reduction of Drug-Related Harm in Vancouver in April 2006 on the topic of "Coverage of Harm Reduction Programmes" (AIDS Project Management Group (APMG), 2006).

So what is meant by the term? And what are the conceptual elements of coverage in the context of interventions for the prevention of HIV among IDUs? At the most simple level, it is important to ask who is being covered and what is being covered? Is coverage a proxy for effectiveness, accessibility and utilisation of interventions – and do they all matter equally? Does coverage refer to any contact, prolonged contact or "effective contact" with a target population? Or does it refer to the coverage of certain behaviours or events – for instance, the percentage of injections with a clean syringe? Is the key issue perhaps to consider who and what is being or not being served.

Another poorly understood area in discussions around intervention coverage is what have been, are and can be the role(s) of the intervention recipients who are to be "covered". Are they passive and compliant partners? What are the necessary conditions, if any for them to be/ become active partners for needed change? It is also crucial to understand that *coverage* has been and will most likely continue to be affected by stakeholders' overt and covert agendas and principles of faith (Brandt and Rozin, 1997). Current discussions of coverage offer a limited understanding of these issues. Most importantly, it is still not clear as to what constitutes adequate or effective coverage (Kral and Bluthenthal, 2003; Bastos and Strathdee, 2000; Des Jarlais and Braine, 2004).

Definitions of coverage

When researchers and international agencies speak of coverage of interventions among IDUs, a wide range of definitions may be used and often authors do not provide a specific definition. For example, in recent papers, the following have been described as "coverage" of NSP:

  1. Individual level:

→ Percentage of injections with a sterile needle and syringe (Aceijas et al Under review;Vickerman and Hickman 2006;Vickerman et al 2006) or any reported re-use of new syringes (Heimer et al 1998;Kral et al 2004).

→ number of syringes retained from last NSP visit multiplied by monthly NSP visits, with this number divided by total monthly injections and multiplying the result by 100. (Bluthenthal et al In press;Bluthenthal et al Under review)

1. Population level:

- percentage of estimated population of IDUs in a geographic area ever reached by a programme (UNAIDS Strategy Meeting 1999;Irwin et al 2006;Burrows 2005)

- percentage of estimated population of IDUs reached in a geographic area by a programme in a specific period (Heimer 2006;Burrows 2006b)

- percentage of estimated population of IDUs in a geographic area reached by a programme on a regular basis (defined variously as either weekly or more than weekly contact) (Aceijas et al Under review;UNAIDS In Press;Burrows 2006a)

1. Services provided to a population: Concerned that many coverage estimations only concentrate on NSP, it has been argued that a comprehensive Spectrum of Services is required to address all aspects of HIV among injecting drug users and that coverage needs to take account of both the services available and IDUs' access to each service component (Aceijas et al Under review;Zheluk and Burrows 2006)

Using the term 'coverage' to mean all of these different aspects of individual and population utilization and access has led to understandable confusion on the part of governments, programmes and researchers. At one point during the Satellite Session referred to above (APMG 2006), it was noted that speakers had variously called for 'coverage' to be increased to 20%, 60% and 80% of IDUs in a given area in order to prevent or stabilize a HIV epidemic. Participants agreed that the three figures could only be correct if the figures referred to very different aspects of coverage.

Usefulness of 'coverage'

Despite the general lack of refection on what it actually means, one must ask why the concept of coverage is so abiding and important in the harm reduction and HIV prevention literature. A lack of adequate coverage has sometimes been used to explain lack of effectiveness of HIV prevention interventions – as in the cases of Vancouver and Nepal (e.g. Strathdee *et al.*, 1997;Strathdee and Vlahov, 2001,Peak *et al.*, 1995). In some cases, there may not be adequate reflection on why HIV prevalence continues to increase in sites which have been known to have a high coverage. A good example of this is Bangladesh, where HIV seroprevalence has continued to increase to from below 2% to 8.9% in one location within a few years; despite coverage rates of between 40–50% (see Azim, Hussein and Kelly, 2005). This paper does not indicate clearly how the term was defined.

Four points are relevant here. First, programme and epidemiological evidence from countries such as Nepal suggests that unless a certain proportion of the 'at risk' population has access to and uses harm reduction interventions, HIV prevention goals may not be attained. Particularly in high HIV/AIDS prevalence regions, if services are not provided to a majority of the 'at risk' population in a geographic area then the entire prevention effort may be jeopardised. Consider the case of Chennai (India) where HIV prevalence increased to over 30 percent among IDUs in 2004 (Panda *et al.,* 2005). The existence of small scale NSPs and a sub-lingual buprenorphine substitution programme which has run for over 7 years has failed to stop the epidemic spreading among IDUs and their sexual partners. Similar experiences have been documented in several locations including China, Myanmar and Manipur (India), (see for example Sharma et al,

2003). In China as of 2004, about 50 NSPs existed, but the HIV prevalence among IDUs has not declined (APMG, 2005). In the Russian Federation, more than 70 NSPs had been established by 2001 yet the rate of HIV among IDUs continues to climb (Burrows 2001): the lack of individual and population coverage of Russian NSPs has been cited as a major cause (Aceijas et al Under review). Thus programmes that do not provide adequate coverage - i.e. do not attract and retain a large proportion of individuals in harm reduction services or do not provide them with adequate syringes - are not likely to be sufficient for controlling HIV transmission.

Second, individual and population coverage remain useful concepts for purposes of monitoring and evaluation in public health interventions, even though the methodologies used to measure them require additional development and testing in the case of HIV prevention interventions.

Third, examining coverage at both the individual and population level resonates key elements of both evidence-based practices and quality improvement frameworks which ask – Is what you are doing likely to work and how might what you are doing be improved? Because assessing individual and population coverage directs us to consider these questions, they can provide both donors and service agencies with shared tools for evaluating the impact of existing interventions and next steps for achieving public health goals.

Fourth, the inspirational imperative associated with the term continues to ensure its preponderance in HIV prevention discourses. Thus, coverage has became a vehicle for advocating for more resources as it serves as a reminder that unless countries scale up demonstration or pilot projects they are unlikely to prevent or reverse epidemics. This has served as a powerful argument with donors and governments alike to channel more resources into expanding effective interventions.

Measuring 'coverage'

The need for some accurate measurement of HIV prevention programmes among IDUs is clear and 'coverage' as an overall term continues to be useful. How then should coverage in HIV prevention programmes among IDUs be measured in a meaningful yet practical way?

Several paths offer some promise. As suggested earlier, it is helpful to consider coverage on two levels at least – the individual and the population. At the individual level, we ask, for those populations who are using programmes, are IDUs receiving enough of the intervention to achieve either behavioral or epidemiological goals? In other words, is the 'dosage' of the intervention adequate? For NSPs this as been measured in two ways. First, a number of investigators have measured whether NSP clients are receiving sufficient syringes to reduce HIV risk by assessing the number of times that new, previously unused syringes are reused. Such an item has been a staple of epidemiological studies of IDUs in the U. S. since the earlier 1990s. The logic behind this item arises from the public health guidance provided by the Centers for Disease Control and Prevention, the U.S. Public Health Service, and the National Institute on Drug Abuse, that have recommended that IDUs use a new sterile syringe for each drug injection. A number of studies have suggested that NSPs that provide higher per visit numbers of syringes have clients that report lower syringe re-use (Heimer et al 1998,Bluthenthal et al 2004;Kral et al. 2004). More recently, a second measure has been developed that assesses the ratio of syringes received from a NSP on a monthly level for each client to that particular clients total number of drug injections. This ratio has so far been expressed as a percentage and provides a more intuitive and perhaps more precise assessment of whether IDUs are receiving sufficient syringes to reduce injection-related HIV risk. Studies that are currently under peer review indicate that NSP clients that achieve individual-level syringe coverage of a 100% or more are significantly less likely to share syringes as compared to IDUs receiving 50% or less syringe coverage (Bluthenthal et al In press;Bluthenthal et al.

Under review). In examination of deciles of syringe coverage, interestingly, investigators found statistically lower rates of syringe sharing were found for NSP clients with coverage percentages above 125% as compared to those with coverage between 90% and 124%, suggesting that at the individual-level saturation of syringes may be required to confidently reduce syringe sharing among drug injectors (Bluthenthal et al. under review). Lastly, examination at the programme level suggest that NSPs that either distribute or supplement syringes exchanged are significantly more likely to have clients with adequate (100% or more) levels of syringe coverage (Bluthenthal et al In press).

At the population level, UNAIDS (2006) have argued that much confusion can be alleviated by substituting 'reach' for 'coverage' in some circumstances. For example, UNAIDS (2006) labels: percentage of estimated population of IDUs in a geographic area ever reached by a program as the "ever reached" figure; percentage of estimated population of IDUs in a geographic area reached by a program in a year as the "annual reach" percentage of estimated population of IDUs in a geographic area reached by a programme on a regular basis as 'regular reach' (this requires a definition of 'regularity': WHO In Preparation defines this as weekly or more often for NSP).

The first two of the above figures can be used for any harm reduction intervention and a unified coding system for service clients (such as the unique identification code, increasingly being used in Central Asia: Gray R. 2006) can ensure that such reach estimates are both accurate and reflect the level of service usage of various service components. Regularity of reach may require different definitions for each service component. 'Regularity' is assumed to point to a level of effectiveness of an intervention. For example, if a NSP attracts an IDU once a year, it is unlikely the drug user is receiving the services he/she wants from the programme. If a methadone consumer stays on a programme for a short while then drops out, this shows that there maybe problems with the programme (Wu 2005).

UNODC is working to develop national coverage indicators that break the concept down into a set of key reach and individual level measurements (personal communication: Dr Christian Kroll, UNODC). A draft version of these indicators shared with the authors (June 2006) reveals that an "essential package" of effective interventions to address HIV among IDUs has been defined as NSP, opioid substitution treatment, voluntary counseling and testing (VCT) and anti-retroviral therapy (ARV), all of which should be specifically targeting IDUs. (An 'Essential Package Plus' has been defined as these interventions plus STI treatment aimed at IDUs.)

Indicators relate to the year in which these services were established; number of sites providing at least one component of the essential package and sites providing all components; number and proportion of estimated IDU population 'covered' by each component and by at least one component; and various methods of estimating coverage for each component. At the draft stage, these include:

NSP: number and proportion of estimated IDU population in weekly or greater contact; average number of needles and syringes provided per contact per client; total number of needles and syringes provided per year; average number of condoms provided per contact per client; total number of condoms provided per year.

Opioid substitution: number and proportion of estimated IDU population on daily substitution for at least 30 days in past year; average dose of substitution drug; separate estimates of both figures for prison opioid users; separate figures for all categories for methadone and buprenorphine; number and proportion of estimated opioid IDU population enrolled in any non-detoxification drug treatment for at least 30 days in the past year.

Treatment, care and support: number and proportion of estimated IDU population receiving VCT in past year; percentage of people receiving VCT who are IDUs; number and proportion of estimated HIV+ IDU population receiving ARV; percentage of people receiving ARV who are IDUs; number and proportion of estimated IDU population receiving STI services in past year.

Education: Number of sites offering targeted information, education and communication (IEC) to IDUs and their sexual partners; number and proportion of estimated IDU population receiving IEC in the past three months.

WHO is working on a longer menu-style list of national indicators from which countries can choose indicators specific to their circumstances (personal communication: Dr Annette Verster, WHO). As part of WHO's work on developing indicators for its Universal Access programme, national AIDS programmes will also be encouraged to set national targets for HIV prevention, treatment, care and support among IDUs.

The level of programme reach/population coverage and individual coverage required for each intervention is likely to be context specific and dependent on several factors such as the stage of the epidemic, the epidemic mix, types and frequencies of risk behaviours, the social and sexual networks of drug users etc. However, internationally there is little available research on how much contact is theoretically necessary to bring about behavioural change. What has been stated frequently in the context of HIV prevention among IDUs is a 60 percent reached figure (based upon a retrospective analysis of the proportion of IDUs that would have been covered) was required to reverse the HIV/AIDS epidemic in New York (see Des Jarlais and Friedman, 2001), where seroprevalence was approximately 50 percent among IDUs. This figure has become a *mantra* in IDU related interventions and has inadvertently led to a stagnation of efforts to arrive at the appropriate reach and coverage levels required in a particular country at a particular point in time. More recently, it has been shown that far lower levels of reach (ranging from 20–30%) may have also led to declines in the prevalence of sharing of injecting equipment (Vickerman and Hickman 2006;Heimer 2006). In a more nuanced assessment of decile ranges of individual syringe coverage, investigators have reported that there was no significant difference in rates of syringe sharing among IDUs with coverage percentage ranges as low as 24% to 39% as compared to IDUs with coverage between 90% and 125% (Bluthenthal 2006b, under review).

Another aspect of coverage is the regularity with which IDUs access services in relation to the number of shared injections or unprotected sex events s/he engages in. If an IDU injects five times a day, and one needle and syringe is provided to him/her in a week, then should one consider that the client is covered? To use a pharmacological term, is the 'dosage' of the intervention adequate? Moreover, is it really feasible to arrive at a universal definition of what might be considered an adequate dose in NSPs? Only if one were to follow the maxim of 'one needle per injection' could there be agreement on this. (In developing countries, resource constraints frequently make this axiom unrealistic, although it should also be noted that this level is rarely reached even in the developed world.) Apart from this consideration, the different methods used for monitoring dosage may make comparisons between sites problematic.

The issue of coverage targets has been addressed by Des Jarlais et al (In Preparation; and Des Jarlais et al 2006), using a modified Delphi process to ascertain what 'harm reduction experts' believe are the essential activities needed to prevent or stabilize a HIV epidemic and the levels of coverage required to be effective. Although not yet finalized, this work has found substantial agreement that the most important components of HIV prevention among IDUs are outreach education, NSP and opioid substitution programmes. It has also found some central tendencies with a majority of respondents suggesting that population coverage or reach levels of 20–33%

are needed for NSP and opioid substitution programmes; and 20–50% for outreach programmes.

Is this enough?

All of the above measurements relate to service delivery or access to services. They do not take account of three important aspects of coverage. The first is the narrow definition of an essential package of services to address HIV among IDUs. Zheluk and Burrows (2006) argue that a comprehensive Spectrum of Services to address HIV among IDUs may require:

- Prevention of drug use and/or injecting

- Needle-syringe programs

- Condom use/safer sex programs specifically targeting IDUs and their sex partners

- Treatment readiness specifically targeting IDUs and their families

- Opioid substitution drug treatment specifically targeting opioid IDUs

- Drug treatment (non substitution) specifically targeting IDUs

- Primary Health Care specifically targeting IDUs

- Police Assistance, ensuring a supportive environment for harm reduction

- Prisons programs specifically targeting IDUs, including pre-release from prison

- Post- release from prison programs

- Voluntary Counselling and Testing specifically targeting IDUs

- HIV/TB treatment, care and support specifically targeting IDUs

- STI treatment specifically targeting IDUs

- Self-support for PLHA specifically targeting HIV positive IDUs

- Socio-legal support specifically targeting IDUs

- Safe spaces specifically targeting IDUs who are also sex workers.

The Spectrum of Services approach is based on the notion that 100% of injecting drug users and sex workers (or as near to this as can be achieved) should be reached on a regular basis by at least one of its components. For example, it is not necessary for needle-syringe programs or opioid substitution programs to regularly reach 100% of injecting drug users but, looking across the complete spectrum, all injecting drug users should be regularly reached (at least weekly) by agencies offering at least one component.

All these components need to be linked in an active referral network so that a drug user (or pre-injector/or at-risk youth) and/or sex worker can enter the Spectrum at any point, participate in relevant and useful services, then be assisted by that programme's staff to move to any other programmes of use to the individual.

While the UNODC draft indicators should capture the most important data for national comparisons, more work will be needed to deal with the variety of drugs of injection, mix of injectors (occasional, recreational, dependent), transitions between drugs and between modes of use, impact of drug policies on drug availability, impacts of policing practices and other factors on drug users' willingness to carry new and used injecting equipment and to access NSP, and many other factors addressing HIV and injecting drug use. Also, it is worth noting that heavy reliance of estimates of populations of IDUs in countries, regions, and sub regions will continue to introduce imprecision into any comparison between countries.

Secondly, the strong preoccupation with numbers of IDUs reached with various services has also taken away from a rigorous discussion about 'quality' and 'standards' within HIV prevention interventions. Clearly it is not just the quantity but also the quality of programmes that impacts on utilization of HIV prevention efforts. Future efforts to define effective individual coverage levels of various interventions will need to concentrate on measuring the quality of services as well as quantity. One attempt to do this in Russian Federation will develop models of monitoring and feedback loops such that local groups of IDUs (through the national IDU organization, *Kolodets*) and local groups of people living with HIV (PLHA, through the national non-government organization *Communities of PLWHA*) will report on harm reduction projects directly to the organization supplying grants to these projects, the Russian Harm Reduction Network. These processes, together with a programme of technical assistance, will be used to try to both monitor and constantly increase quality of the projects (personal communication: Vitaly Djumagaliev, RHRN).

Thirdly, all of the processes described thus far have concentrated on services rather than on behaviour. There are good reasons for this. Through funding and other mechanisms (national monitoring and evaluation systems for example), programmes can be used to provide estimates of population sizes (IDUs, opioid IDUs, etc) and to produce accurate reports of the numbers reached with various services. This can all be carried out without expensive behavioural research. But ultimately, it is the risk behaviour itself which needs to be reduced and maintained at a low level. In the past (as we saw above), several service/behavioural measurements have been labeled as 'coverage'. An example of a combined service/behavioural indicator is "the number of sterile syringes provided to an injecting drug user divided by the estimated number of injections during a specified time frame" (UNAIDS, 2006). While this measure seems rigorous, it requires considerable baseline information such as estimates of: the number of IDUs, the average number of injections per day per IDU, and the number of available needles and syringes (including those from additional sources like pharmacies and friends) etc. Such information is prone to errors and is frequently not available. Another option is using information collected by the programmes themselves on the service utilization, drug use patterns, and HIV risk behaviors of their clients. Many of the most recent studies that have examined individual syringe coverage and syringe re-use collected data at NSPs using short surveys. While this amount of data collection is likely beyond the capacity of most NSPs, it is worth noting that both syringe re-use and individual syringe coverage percentages can be collected in as few as one or two items depending on the sophistication and recording tracking system of the NSP in question. For instance, to assess syringe re-use, we would ask: Have you reused any of your new syringes in the last 30 days? And how many times have you injected drugs (including intramuscular or skin popping injections) in the last 30 days? And then use programme information on client visits and syringes received in a monthly period to assess the relationship between any syringe reuse and client services. Individual syringe coverage as described by Bluthenthal et al, could be assessed by one item (number of injections) using this same system.

Finally, there are mathematical and epidemiological models for coverage, which are highly complex and not accessible to those who usually run such programmes (see for example, Vickerman and Watts, 2002;Vickerman and Watts, 2003). Parameters of models of coverage are also highly vulnerable to changes in drug use patterns. For example, those switching from heroin injection to cocaine injection are likely to have a much higher injection frequency and altered sexual risk. Epidemiological models of coverage are frequently not sensitive to these fluidities.

Conclusion

Should there be one ubiquitous coverage indicator or does it make more sense to follow the example of coverage assessments in immunization where the purpose of measuring up-to-date immunization coverage determines the way that it is measured (Fairbrother, Freed and Thompson, 2000)? Or should we break down coverage indicators for HIV prevention among IDUs by availability, accessibility and utilisation of services?

For national assessments of coverage, we would argue that assessing population coverage (availability and accessibility) and individual coverage (patterns of utilization) appear to be the most promising approach. Aspects of this are included in both the UNODC indicators as well as the more comprehensive Spectrum of Services approach. Nonetheless, authorities in specified geographic areas (whether countries, provinces, districts or cities) and individual projects will need to work on monitoring processes beyond the basic data required. Measurement of availability, access to (and/or utilization of) all components in the necessary Spectrum of Services for that place at that time; measurement of quality, and combining service indicators with behavioural research will all be needed.

The challenges in defining and measuring coverage have long been identified. The question that confronts those working in HIV prevention is whether a serious effort should be made now to grapple with these complexities or to continue to pay lip service to a concept that remains ill defined and elusive. If HIV prevention programmes are to move beyond "boutique" programmes to effective scaled interventions that are adequately resourced, then attempts to answer the questions raised here must be made urgently.

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