OPERATIONAL GUIDELINES
FOR MONITORING AND
EVALUATION OF
HIV PROGRAMMES
FOR PEOPLE
WHO INJECT DRUGS

Monitoring and evaluation at the
national and subnational level

DRAFT
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Abbreviations

AIDS  ACQUIRED IMMUNODEFICIENCY SYNDROME
CDC  CENTERS FOR DISEASE CONTROL AND PREVENTION
DFID  UK DEPARTMENT FOR INTERNATIONAL DEVELOPMENT
HIV  HUMAN IMMUNODEFICIENCY VIRUS
ICASO  INTERNATIONAL COUNCIL OF AIDS SERVICE ORGANIZATIONS
M&E  MONITORING AND EVALUATION
MERG  MONITORING AND EVALUATION REFERENCE GROUP
NGO  NONGOVERNMENTAL ORGANIZATION
PLACE  PRIORITIES FOR LOCAL AIDS CONTROL EFFORTS
TB  TUBERCULOSIS
UNAIDS  JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS
UNDP  UNITED NATIONS DEVELOPMENT PROGRAMME
UNFPA  UNITED NATIONS POPULATION FUND
UNGASS  UNITED NATIONS GENERAL ASSEMBLY SPECIAL SESSION
UNODC  UNITED NATIONS OFFICE ON DRUGS AND CRIME
USAID  UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT
WHO  WORLD HEALTH ORGANIZATION
Introduction

Purpose of the operational guidelines

The purpose of these guidelines (hereafter referred to as “the Guidelines”) is to provide advice and tools for people and organizations planning, managing or implementing monitoring and evaluation (M&E) activities in support of HIV programmes for people who inject drugs.

The objectives are to:

- recommend appropriate data-collection methods that address the unique information needs of programme managers at the national, subnational and service delivery level;
- outline methods that involve people who inject drugs to improve HIV prevention programming;
- offer adaptable tools for local contexts;
- describe examples of data collection from field experiences;
- provide links to additional resources.

The Guidelines are a companion document to *A framework for monitoring and evaluating HIV prevention programmes for most-at-risk populations* (UNAIDS, 2007a; hereafter referred to as “the Framework”). Both documents aim to operationalize the guiding principles and conceptual foundation of the Framework by describing how to implement M&E of HIV prevention for people who inject drugs. The Guidelines also complement the work of WHO, UNODC and UNAIDS presented in *WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users* (WHO, 2009a; hereafter referred to as “the Target setting guide”).

As there is no single way to implement M&E activities, applying the Guidelines in practical settings and different contexts will be carefully documented over the next year and the Guidelines updated accordingly. All comments and feedback are welcome and can be sent to the Response, Monitoring and Analysis Team, UNAIDS, Miriam Lewis Sabin at: sabinm@unaids.org.

Content of the operational guidelines

The Guidelines contain the following sections:

- **A section intended for all levels (national, subnational, service delivery).** This section describes the overall objectives of a comprehensive HIV prevention programme for people who inject drugs. It provides an overview of the key data needed to understand the HIV epidemic in this subpopulation and to assess whether the response adequately addresses the population’s needs and ultimately reduces the HIV epidemic. The section introduces the organizing framework used throughout the Guidelines, focusing on eight basic questions in the programme design and management cycle to support evidence-based decision-making.

- **A section focused specifically on the national and subnational levels.** This part describes the specific data needed at the national and subnational level to ensure a comprehensive, effective and efficient HIV programme for people who inject drugs. It discusses detailed data-collection methods to track the epidemic, to monitor progress towards specific targets, and to evaluate whether policies and programmes are positively affecting vulnerability and risk for HIV transmission and reducing the HIV impact. The concrete examples and key tools will help to put in place the necessary data-collection efforts or strengthen already existing M&E systems.

1 See also UNAIDS, 2007.
A section intended for the service delivery level. This part focuses on specific methods and tools for good programme management, with the aim of providing good-quality services to as many people in need as possible. It also describes which data collected at the national or subnational level may be useful to inform the delivery of services.

The tools section compiles all tools referenced throughout the Guidelines.

The appendices contain a glossary of the M&E terms used throughout the Guidelines and useful reference materials about M&E, including a list of existing indicators.

The following information is presented on each of the eight key questions (also referred to as “steps”) to be addressed by M&E data collection:

- importance and specific objectives of the data to be collected;
- overview of the data-collection methods, data products and their use;
- concise descriptions of how data are collected, including references to specific tools provided in the tools section or in links to additional resources;
- examples of data analysis and data use, where possible.

Intended users of the operational guidelines

The Guidelines are relevant to the following key audiences:

- national and subnational programme managers responsible for HIV programmes for people who inject drugs;
- focal points at the national and subnational level responsible for M&E of the HIV response, including HIV surveillance;
- managers and staff responsible for facility- or community-based services targeting people who inject drugs or serving a range of clients that include people who inject drugs;
- people managing or implementing M&E of services for people who inject drugs;
- people who inject drugs and their interest groups;
- organizations that fund HIV programmes, including international donor agencies.

Using the operational guidelines

The Guidelines address the unique needs of settings where HIV affects people who inject drugs. The Guidelines apply to countries with low-level or concentrated HIV epidemics; they also apply to countries with generalized HIV epidemics. In low-level and concentrated HIV epidemics, it is important to prioritize resources for the populations most infected with and affected by HIV. In generalized epidemics, a broad response is needed but must include effective efforts to reduce high rates of HIV transmission among vulnerable populations, which may include people who inject drugs.

The Guidelines are intended to improve the availability, timeliness and quality of data for decision-making in HIV programmes for people who inject drugs, with a focus on addressing the following key questions: (1) Are we doing the right things? (2) Are we doing them right? (3) Are we doing them on a large enough scale to reduce the problem? The focus is on the collection and use of data to maximize the positive effects of HIV-related policies and programmes for people who inject drugs.
The Guidelines can be used to:

- review existing M&E data about people who inject drugs, and the policies and programmes that aim to reduce HIV transmission among them, in order to identify important data gaps and implement appropriate methods and tools to address these gaps;
- improve involvement of people who inject drugs in programme planning and M&E;
- prioritize the implementation of M&E activities that provide data for programme improvement;
- improve procedures for data quality assurance;
- improve procedures for timely sharing of relevant data between national, subnational and service delivery levels;
- help analyse, interpret and act on data for programme improvement.

**HIV prevention for people who inject drugs, and M&E for programme planning and improvement**

**Continued need for HIV prevention among people who inject drugs**

The 2010 UNAIDS report on the global AIDS epidemic and Mathers et al. (2010) present the most recent regional data and estimates on the HIV epidemic among people who inject drugs:

- **Asia:** It is estimated that as many as 4.5 million people in Asia inject drugs. More than half of these people live in China. India, Pakistan and Viet Nam also have large numbers of people who inject drugs. On average, an estimated 16% of the people who inject drugs are living with HIV, although the prevalence is much higher in some countries (e.g. up to 38% in Myanmar, 30–50% in Thailand, 32–58% in Viet Nam).

- **Caribbean:** In Bermuda and Puerto Rico, unsafe injecting drug use contributes significantly to the spread of HIV. In Puerto Rico, contaminated injecting equipment accounted for about 40% of new infections in males and 27% of new infections in females in 2006.

- **Eastern Europe and central Asia:** An estimated one-quarter of the 3.7 million people who inject drugs in this region are living with HIV, most of whom are men. In the Russian Federation, 37% of the country’s estimated 1.8 million people who inject drugs are believed to be living with HIV, compared with 39–50% in Ukraine. The interplay between sex work and injecting drug use is accelerating the spread of HIV in the region. For example, at least 30% of sex workers in the Russian Federation have injected drugs, and the high HIV infection levels found among sex workers in Ukraine (14–31% in various studies) are almost certainly due to the overlap of paid sex and injecting drug use. Sharing contaminated injecting equipment remains a core driver of these epidemics. An estimated 35% of women living with HIV probably acquired the virus through injecting drug use; an additional 50% were probably infected by partners who inject drugs.

- **Middle East and north Africa:** Reliable data on the epidemics in this region remain scarce. The Islamic Republic of Iran is believed to have the largest number of people who inject drugs in the region, and its HIV epidemic is centred mainly within this population. An estimated 14% of people who inject drugs countrywide were living with HIV in 2007. Exposure to contaminated drug-injecting equipment features in the epidemics of Algeria, Egypt, Lebanon, the Libyan Arab Jamahiriya, Morocco, Oman, the Syrian Arab Republic and Tunisia.

- **North America and western and central Europe:** The total number of people living with HIV in these regions continues to grow, but rates of new infections among people who inject drugs have been falling overall, due largely to harm-reduction services. In the Netherlands and Switzerland, for example, HIV infections due to “social” drug use (several people using the same contaminated
injecting equipment) have almost been eliminated. At most, 5% of new infections were linked to injecting drug use in 2007 and 2008. The epidemic is also declining among people who inject drugs in north America. Using contaminated drug-injecting equipment can still dramatically accelerate an HIV epidemic, as in Estonia: Hardly any people newly infected with HIV were detected there a decade ago, but within a few years the majority of surveyed people who inject drugs (up to 72%) were living with HIV. There are also flashpoints along the border between Mexico and the United States of America, where intersecting networks of drug use and paid sex appear to drive the spread of HIV. These localized epidemics have considerable potential to grow.

- **Oceania**: Injecting drug use is a minor factor in the epidemics in this region. In parts of Australia, however, injecting drug use is commonly seen in the HIV epidemic among Aboriginal people. HIV infection among Aboriginal and Torres Strait Islander people was attributed to injecting drug use in 22% of cases over the past 5 years. In French Polynesia and Melanesia (excluding Papua New Guinea), people who inject drugs comprise 12% and 6%, respectively, of cumulative HIV case reports.

- **South and central America**: Most of the HIV epidemics in this region are concentrated in and around networks of men who have sex with men, but injecting drug use is the other main route of HIV transmission. It is estimated that as many as 2 million people inject drugs in this region and that more than a quarter of these may be living with HIV.

- **Sub-Saharan Africa**: Injecting drug use is a relatively recent phenomenon in this region, featuring in countries such as Kenya, Mauritius, Nigeria, South Africa and the United Republic of Tanzania. Available research shows high HIV prevalence among people who inject drugs: 36% in Nairobi, 26% in Zanzibar, 12% in South Africa and 10% in the Kano region of Nigeria.

**Box 1**

Universal access to HIV-related services

People who inject drugs have the right to access high-quality services for HIV prevention, treatment, care and support. Involving people who inject drugs in the planning, delivery and evaluation of HIV-related services ensures a better understanding of the specific dynamics of the HIV epidemic among them and how best to address their needs (WHO, 2009a).

People who inject drugs have the right to access high-quality services for HIV prevention, treatment and care (Box 1). However, few countries currently know the size of the population of people who inject drugs, and few countries know the HIV prevalence among the population in order to estimate service needs. There is also limited information on the implementation of services for the prevention and treatment of HIV infection among people who inject drugs. Few countries monitor the determinants of HIV transmission, and even fewer monitor the coverage and quality of services delivered. Very few countries rigorously assess whether the services actually prevent HIV transmission.

In 2008, of 149 low- and middle-income countries, only 41 countries reported systematic surveillance of HIV among people who inject drugs, and only 19 countries reported on coverage of HIV prevention services for people who inject drugs (UNAIDS, 2010a).

The lack of data is problematic, because human suffering associated with HIV and acquired immunodeficiency syndrome (AIDS) and limited resources demand evidence-based programme planning. Continued improvement to maximize programme effects will reduce the epidemic and its impact on people who inject drugs. The Guidelines aim to strengthen data collection, analysis and use.
Making HIV programmes work: Importance of a programme impact pathway

Every programme manager should construct and regularly review the **programme impact pathway** (also referred to as the programme logic model). This should be used for planning, implementation and M&E of the programme. The programme impact pathway draws on existing evidence and on-the-ground experience with what works. It describes the main programme elements and how they are intended to work together to reach measurable objectives deemed important in HIV prevention among people who inject drugs.

The first step in specifying appropriate HIV programmes for people who inject drugs is to identify which of the biological determinants of HIV transmission the programme aims to change. A programme can reduce HIV transmission only if it achieves one or more of the following desired outcomes or changes in the biological determinants:

- reduce the number of people who inject drugs;
- reduce the number of young people who start injecting drugs;
- reduce the frequency of injections;
- reduce the use of non-sterile injecting equipment;
- increase the use of sterile injecting equipment;
- reduce the viral load of people who inject drugs who are already infected, including the availability and use of antiretroviral therapy;
- reduce the number of sexual partners of people who inject drugs;
- increase the use of condoms among people who inject drugs;
- increase the effective treatment of sexually transmitted infections.

Some indirect determinants must also be addressed for HIV programmes. Poverty, lack of education and a stigmatizing environment, for example, may make people more vulnerable to or at increased risk for HIV infection. These sociodeterminants need to be clearly understood in order to identify points of intervention to remove barriers to safer behaviour. Sociodeterminants may include:

- restrictive laws and policies;
- stigma and discrimination;
- lack of involvement of people who inject drugs in programme planning and implementation;
- poverty;
- illiteracy;
- lack of social support;
- violence;
- political instability;
- comorbid conditions that affect vulnerability (e.g. poor mental health).

Figure 1 summarizes the causal pathway between programmes and reduced HIV transmission. Programmes aim to remove sociodeterminants that are barriers to achieving the desired outcomes and promote factors that reduce risk behaviours. Effective programmes reduce the biological determinants of HIV transmission and thus prevent new infections.
Although there is strong evidence for the effectiveness of different programme elements in HIV prevention for people who inject drugs, no single programme component is sufficient to reduce HIV transmission at the population level. Programme components not intended to avert HIV infection directly should be integrated with other programmes. This ensures that, together, they are accountable for significantly reducing new HIV infections. There is a need for joint planning at the national and subnational level to ensure that the right mix of interventions is provided in each area in need.

The programme impact pathway for the overall national or subnational HIV programme and the service delivery settings can help to describe the way in which the programme is supposed to run and the results that can be expected, barring unforeseen barriers and changes (i.e. “if all goes as planned”). Any changes in the programme (e.g. changes in funding or shifting priorities) can lead to suboptimal programme implementation and different results from those anticipated. Accurate documentation is important to understand how the programme has worked or not worked. The programme impact pathway can help to identify which data need to be collected throughout the programme.

Need for a comprehensive approach to addressing HIV among people who inject drugs

Reducing the HIV epidemic among people who inject drugs requires a comprehensive approach. The recommended comprehensive package of services endorsed by key organizations (including UNAIDS, UNODC and WHO) includes the following services:

- needle–syringe programmes;
- opioid substitution therapy and other drug-dependence treatment;
- HIV testing and counselling;
- antiretroviral treatment;
- targeted information, education and communication;
- condom promotion for people who inject drugs and their sexual partners;
- prevention and treatment of sexually transmitted infections;
- vaccination, diagnosis and treatment of viral hepatitis;
- prevention, diagnosis and treatment of tuberculosis (TB).
These nine interventions are included in the comprehensive package because they have the greatest impact on HIV prevention and treatment outcomes. There is a wealth of scientific evidence supporting the efficacy of these interventions in preventing the spread of HIV.

In addition, structural and community reforms need to be undertaken to create an environment conducive to successful provision of the recommended services:

- Remove legal barriers to service access and use.
- Train and sensitize service providers to ensure services are user-friendly.
- Conduct community mobilization and ensure participation from people who inject drugs in the planning, delivery and evaluation of services.
- Establish safe spots to ensure that members of the populations that are most at risk can access places staffed by supportive individuals to obtain information about services without fear of being stigmatized.

Such combinations of HIV prevention services are rights-based, evidence-informed and community-owned to meet the HIV needs of the population. Well-designed combination HIV programmes (1) are tailored carefully to national and local needs and conditions; (2) focus resources on a mix of programmatic and policy actions required to address both immediate risks and underlying vulnerability; and (3) are thoughtfully planned and managed to operate synergistically and consistently on multiple levels (i.e. individual, relationship, community, society). Combination HIV programmes mobilize local community, private sector, government and global resources in a collective undertaking; require and benefit from enhanced partnership and coordination; and incorporate mechanisms for learning, capacity-building and flexibility in order to permit continued programme improvement over time (UNAIDS, 2010a).

Figure 2 provides an overview of the programme impact pathway for HIV prevention services for people who inject drugs. Programme managers at national and subnational levels should ensure that people who inject drugs have access to all needed services and in appropriate locations, and that data on inputs, outputs, outcomes and impacts are collected.

Managers at the service delivery level will most likely provide a selection of the services, depending on the delivery setting (e.g. stand-alone, non-clinical setting, clinical setting, outreach setting) and may refer clients to other service delivery sites to obtain additional services that are provided on site. Service providers are responsible for data collection of inputs and outputs, as shown in Figure 3.
Problem statement: HIV prevalence continues to be high among people who inject drugs and shows regional variation, ranging from 16% in area A to 32% in area D. Consistent condom use with sex workers is reported to be 66%, and condom use at last sex with a regular sex partner is reported to be 23%. Injecting drug use is a criminal offence and 33% of health-care providers report discriminatory attitudes towards people who inject drugs. Interventions with proven effectiveness in increasing service use and reducing risk behaviours have not been implemented fully.

External factors that may affect implementation need to be specified as well as assumptions about/evidence for the proposed interventions and their causal linkages.

Illustrative data only.

The operational definition of the package of services to be provided should be clearly formulated at national level.
Plan, monitor, evaluate: Who needs to do what?

The Guidelines use the public health questions approach to HIV M&E (see Figure 4) as the guiding framework to identify data needs and data collection efforts. Good evidence is already available from evaluation studies on the positive effects of different programme elements (e.g. needle–syringe programmes) on changing behaviours or preventing HIV transmission among people who inject drugs. Consequently, these programme elements must be scaled up in an integrated way to address the various needs of the target population, with good quality and high coverage, and to assess whether the combined effects of all programmes are achieving, or continue to achieve, their intended ultimate effect of reducing HIV transmission.
A strategic and phased approach is needed to support HIV prevention for people who inject drugs. Not everything can be done at once, and not everyone or every level needs to conduct all aspects of M&E. The roles and responsibilities of programme managers at the national and subnational level are different from those at the service delivery level. These specific roles and responsibilities are indicated below and explained in detail throughout the Guidelines; they are also the reason for providing operational guidance specifically for each level. Even if programme managers do not collect the data, they must still understand what data are needed in order to guide the selection of appropriate M&E methods, to provide oversight of their implementation, and to use the data for programme improvement. Programme managers at different levels do not work in isolation but contribute to the same overall programme and programme objectives.
Plan: What should we be doing to reduce HIV transmission among people who inject drugs?

Steps 1–3 obtain necessary information for planning the intervention response and setting targets at the national, subnational and service delivery level. Objectives are to:

- describe the epidemiology of the HIV epidemic among people who inject drugs in the country;
- identify the factors that increase HIV transmission, including environmental factors;
- identify differences in HIV rates in different subnational areas;
- estimate the number of people who inject drugs in each subnational area;
- estimate baseline outcome and impact indicators and set targets;
- specify the services required in each subnational area to achieve targets.

The national and subnational levels are usually responsible for collecting data to understand the epidemic and sociodeterminants. Service providers need to use these data to be able to plan and set targets for their service provision.

Monitor: What services and interventions are we implementing? Are we implementing them right?

Steps 4–6 describe how to implement a system to monitor programmes at the national, subnational and service delivery level. Objectives are to:

- assess whether programme inputs are adequate to meet output targets;
- document the outputs achieved;
- estimate the proportion of people who inject drugs that access services;
- assess the quality of the services that are provided.

Evaluate: Are our programmes effective?

Steps 7–8 describe how to evaluate whether a prevention programme has indeed prevented HIV transmission at the national and subnational level. Objectives are to:

- analyse and interpret data collected from routine monitoring at the service delivery level and from targeted integrated biobehavioural surveys;
- synthesize the findings with specific recommendations that can be used for programme planning, resource allocation and programme improvement.

Figure 5 illustrates a possible timeframe for the different M&E activities. This M&E cycle should be coordinated with the country’s programme planning and implementation cycle so data are available in a timely fashion to support evidence-based decision-making.
Ensuring ethical conduct

Ethical conduct and regard for the welfare of people involved in M&E activities and people affected by their results are of utmost importance. M&E must generate useful information, while ensuring the available data do not worsen discrimination and stigma towards people who are living with HIV (De Lay and Manda, 2004).

Protection of participants should be exercised when conducting any M&E, surveillance or research activities. Special protection is warranted when key populations are involved. These populations may already be socially vulnerable or marginalized for their behaviours. Data-collection efforts that identify or bring attention to these populations may place them at additional risk. For example, in many countries, it is not possible to admit to drug use without increasing the risk of being incarcerated.

All people should be respected and treated as autonomous individuals who can and should freely make decisions regarding their participation in M&E activities. Those directing M&E efforts should maximize the benefits and minimize any potential harm from these activities. Individuals involved in planning or implementing M&E activities have ethical and legal obligations to protect the privacy of the participants. They must clearly explain to participants how they will protect and use private information. In this context, privacy refers to the control of information about an individual by that individual – and the right to control information about oneself is an aspect of autonomy. Some common procedures that ensure that these principles are achieved include informed consent (see Box 2), safeguards of private information, and protection of human subjects review by an institution authorized to do so.
Operational guidelines for monitoring and evaluation of HIV programmes for people who inject drugs

Box 2
Key elements of informed consent

Informed consent should include:

- an explanation of the purpose of the project or study, with a description of the procedures involved;
- a description of the foreseeable risks or discomforts to the participants;
- a description of any compensation to be given;
- an explanation of whom to contact with questions;
- a statement of any benefits to the participants;
- a statement about the confidentiality of records.

Procedures must be used to ensure the confidentiality and protection of private information. These procedures may include conducting interviews in private spaces, using identification numbers rather than names to refer to individuals, and storing private or individually identifiable information in a secure environment. The Guidelines recommend the use of a unique identifier code for each individual accessing a service; this guarantees that data cannot be linked directly to a specific person and allows for better tracking of service use.

In some cases, M&E activities may require a formal review of the protection of the rights of human subjects. Data-collection activities that are classified as research require a review by qualified individuals or institutions to ensure that the study protocol and procedures will protect the rights of human subjects.

Participatory approach to service planning, delivery and M&E

Participation of stakeholders (individuals, groups or communities with a stake or vested interest in the programme) is crucial. The participation of people who inject drugs in the planning, delivery and M&E of services requires special attention and continued effort. The Guidelines recommend involving the target population in obtaining information and providing feedback to ensure that services are provided in the most appropriate locations, are user-friendly and serve the population’s needs. Often, people who inject drugs are also peers in the delivery of services, especially in outreach settings.

Ensuring meaningful participation of people who inject drugs is not clear in all contexts. It is necessary to better document how this can be done and to learn from each other’s experiences.

Selecting appropriate indicators

Indicators provide critical information about programme performance. If the indicators are not selected strategically, however, they may be of limited value or too many resources may be required to collect them. Indicators should generate data that are needed and useful. A useful indicator tells programme managers that their programme works or needs to be changed to better meet its objectives. Indicators should be chosen that provide credible data. Indicators are often part of an indicator set that measures different elements of a programme to describe the extent to which the programme is achieving its objectives. Typically, it is best to start with a few indicators that provide key information about the programme, that can be well defined so that they can be collected in a standardized manner and with good quality, and that can be measured repeatedly to provide trends over time. Once the basics are in place, additional indicators may be added, if needed, and as resources and capacity permit.
Throughout the Guidelines, specific recommendations are made to help with the selection of appropriate indicators. Annex 2 lists indicators that can be used at the national, subnational or service delivery level. As the focus of the Guidelines is primarily on HIV prevention, indicators for treatment, care and support programmes are not included here. M&E of individuals enrolled in HIV care and treatment programmes should follow existing national programme protocols.

United Nations Global AIDS Response Progress Reporting (GARPR) indicators need to be part of the national indicator set. All countries signed the Political Declaration on HIV/AIDS in 2011 thus agreeing to provide biennial progress reports. All countries should also track indicators of national commitment, such as HIV-related expenditure and national strategies, policies and laws focused on the needs of populations that are most at risk in general, and the needs of people who inject drugs in particular. In accordance with the “Three Ones” principles (UNAIDS, 2005), countries are working towards one country-level M&E system. Applying this principle to indicator selection means that indicators should be selected as much as possible from the existing global AIDS indicator set from 2011, previously referred to as UNGASS national and programme-specific indicator sets, rather than developing new indicators.

Ensuring data exchange between the national, subnational and service delivery levels

Although the different programmatic levels have different roles and responsibilities for collecting data, they are interdependent. The national and subnational levels need to share information about the course of the epidemic with service providers for them to be able to target services appropriately. Service providers need to share information about the reach and quality of the services provided so that the national and subnational levels can ensure a comprehensive and coordinated response.

Some of this information is reported regularly (e.g. monthly or quarterly) by all service providers to subnational levels, which then report to the national level. Feedback on progress made toward set targets and on data quality is then given. Box 3 lists the information needed for each service site that helps to determine whether there is a reasonable match between the needs for services and the services actually provided.
### Box 3

**Minimum information and indicator data about service delivery for regular reporting to the subnational level**

<table>
<thead>
<tr>
<th>Subnational area:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and physical address of service delivery site</td>
<td></td>
</tr>
</tbody>
</table>
| Period covered by this report (month or quarter) | From (date):  
To (date): |
| Type of service delivery site |  |
| Services provided in past month (tick all that apply) | Needle–syringe programme  
Opioid substitution therapy  
Targeted information, education and communication  
HIV testing and counselling  
Antiretroviral treatment  
Condom distribution  
Diagnosis and treatment of sexually transmitted infections  
Viral hepatitis services  
TB services  
Referral to HIV testing and counselling  
Referral to clinical services |
| For each service provided, number of individuals receiving each service in past month/quarter | Needle–syringe programme  
Opioid substitution therapy  
Targeted information, education and communication  
HIV testing and counselling  
Antiretroviral treatment  
Condom distribution  
Diagnosis and treatment of sexually transmitted infections  
Viral hepatitis services  
TB services  
Referral to HIV testing and counselling  
Referral to clinical services |
| If available | Number of individuals that are first-time visitors  
Number of individuals that are repeat visitors |
| Comments | Service delivery issues  
Data-collection issues |
Additional resources: HIV prevention, M&E and related indicators


Monitoring and evaluation at the national and subnational level

Step 1: Know your epidemic. What are the nature, magnitude, geographical distribution and course of the HIV epidemic among people who inject drugs?

**Overview**

**Rationale: Why is this step important?**

People who inject drugs are often a hidden population. Many are young, homeless and estranged from their families. Without a concerted effort to uncover and address the problem of injecting drug use, unknown local HIV epidemics will continue to affect many lives. In Step 1, a national investigation of the nature, magnitude, geographical distribution and course of the HIV epidemic among people who inject drugs is undertaken to guide proper and effective national response.

**Objectives: What will this step help you do?**

- Describe the problem of injecting drug use in the country.
- Define the population of people who inject drugs that will be used in M&E.
- Describe the HIV epidemic among people who inject drugs.
- Describe the geographical distribution and the size of the population of people who inject drugs.

---

**Figure 6 Step 1: Know your epidemic**

<table>
<thead>
<tr>
<th>Key questions</th>
<th>Methods</th>
<th>Products</th>
<th>Data use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 What is the evidence that injecting drug use is a problem in the country?</td>
<td>Conduct a situational analysis and hold a National Forum</td>
<td>Documentation of injecting drug use in the country</td>
<td>A strong consensus statement can raise awareness and result in demand for improved monitoring of programmes</td>
</tr>
<tr>
<td>1.2 What definition of the population will be used for monitoring? Which sub-groups will be monitored?</td>
<td>Compare international guidelines and national practice</td>
<td>One standardized definition for the country</td>
<td>The standard definition allows indicator comparability and data aggregation across levels</td>
</tr>
<tr>
<td>1.3 What information is available about the extent of HIV infection among people who inject drugs?</td>
<td>Synthesize existing prevalence data Estimate HIV incidence</td>
<td>HIV prevalence and incidence by area and sub-groups</td>
<td>Indicators used to evaluate the impact of HIV prevention programmes</td>
</tr>
<tr>
<td>1.4 What is the geographic distribution of the population? How many people inject drugs in each sub-national area?</td>
<td>Use size estimation methods Map PWID</td>
<td>Map of the geographic distribution of PWID with size estimates</td>
<td>Size estimates inform need for services. Maps show where services are needed</td>
</tr>
</tbody>
</table>
How to answer key questions

1.1 What is the evidence that injecting drug use is a problem in the country?

**Products**

*Documentation of injecting drug use in the country*

Documentation of the problem of injecting drug use in the country includes a description of what is known about injecting drug use. It also includes a consensus statement from relevant stakeholders on the extent of the problem.

**Methods**

The first step in developing an effective HIV prevention programme for people who inject drugs is to assess whether there is an injecting drug use problem in the country. It is also important to understand the characteristics of the problem.

*Use the Rapid Assessment and Response method*

The Rapid Assessment and Response method is a way to thoroughly assess a public health problem in a particular geographical area. In this context, the method can be used to define the characteristics of injecting drug use in the country, the population groups affected, the settings and contexts where the injecting drug use occurs, the specific health and risk behaviours involved, and the social consequences of the injecting drug use problem. The Rapid Assessment and Response method is often used where:

- current data are needed to develop and implement intervention programmes;
- data are needed quickly;
- time or cost constraints rule out other, more in-depth, systematic assessment methods (e.g. population-based surveys, determinants research).
**Convene a national forum to analyse the situation and to agree on the way forward**

A national forum including people from the target population and people from governmental organizations, nongovernmental organizations (NGOs) and other international organizations knowledgeable about people who inject drugs should be organized. Discuss what is known about injecting drug use in the country. This forum should address the following key topics:

- description of the injecting drug use problem in the country (based on existing data collected through various methods);
- description of the illegal drugs most frequently injected, and the sources of these drugs;
- cities and districts with known injecting drug use problems and their local contexts;
- insights into the characteristics of people who inject drugs;
- legal issues including relevant law enforcement reports from the national and subnational level;
- description of existing facility- and community-based services for people who inject drugs.

The national forum should result in a consensus statement covering:

- what is known about injecting drug use in the country;
- the key information gaps;
- the resources available for interventions and services and for M&E;
- the next steps for addressing the injecting drug use problem.

A national forum is an excellent way to periodically bring together relevant stakeholders to share information and to agree on a way forward. A more permanent structure for ongoing sharing of ideas and communication regarding drug use should also be considered to stay abreast of new developments. Ideally, this function is incorporated into the responsibilities of an existing national body or stakeholder group.

**Data use**

Some countries have injecting drug use on the national agenda, but in other countries the issue is hidden. A consensus statement among all relevant stakeholders raises awareness about the problem of injecting drug use with policy-makers and the public, provides input for decision-making about HIV prevention among this group, and allows for active participation of all sectors and stakeholder groups.

Ongoing information-sharing and communication alerts relevant stakeholders to new developments that may need to be addressed in a collective response.

Examples of how data have been used at the country level to inform HIV prevention, care and treatment programmes among people who inject drugs should be incorporated into the national, subnational and service delivery M&E training.

**Additional resources: Situational analysis and rapid assessments**


1.2 What definition of the population of people who inject drugs will be used for monitoring HIV prevention programmes? Which subgroups will be monitored?

**Products**  
*Standard definition of the population of people who inject drugs*

Countries should consider adopting the international standard definition for the population of people who inject drugs: "Those who have self-injected drugs at any time within the past 12 months". This definition excludes people who self-inject medicines for medical purposes. The definition does not discriminate between people based on the type of drug injected, sex or age.

**Methods**  
*Compare international guidelines and national practice*

Results from situational assessments and additional information obtained during stakeholder meetings can be reviewed to clarify the definition of a "person who injects drugs". This is important because a vague definition leads to confusing data collection and interpretation. Agreement on one working definition of the target population is essential for defining standardized indicators (i.e. indicators that are measured in the same way, regardless of who measures them) and for interpreting trends over time. A clear definition should be given to, and used consistently by, service providers for data that must be shared with the subnational and national levels. This allows for comparison between service providers and geographical areas and over time. The definition of a "person who injects drugs" can be changed for local monitoring purposes; however, one standardized definition must be used for subnational, national and global monitoring purposes.

The Guidelines recommend that countries monitor all HIV prevention indicators by geographical area, sex and age. There are no specific recommendations for monitoring subgroups by type of drug injected or currently receiving opioid substitution therapy; however, each country should review whether it makes sense to monitor subgroups by type of drug injected or other characteristics.

A table shell (see Tool 1) is useful to operationalize and communicate decisions about definitions and subgroups for monitoring purposes. This table shell is used in the rest of Step 1 and all the following steps to guide reporting of indicators.

1.3 What information is available about the extent of HIV infection among people who inject drugs?

**Products**  
*HIV prevalence trends among people who inject drugs*

A table of HIV prevalence trends among people who inject drugs by geographical area, age and other important subgroups should be created. This table should provide information on the methods used to collect the data and to make estimates.

**Methods**

Trends in HIV incidence and prevalence by geographical area, age and other important subgroups are the standard method for monitoring the HIV epidemic in key populations.  

**HIV incidence** is the number of new HIV infections over a period of time in a defined population initially free from infection. For example, an annual incidence of 5% among people who inject drugs
indicates that 5% of all people who inject drugs who are initially uninfected at the beginning of the year became infected during that year. HIV programmes should aim to reduce the number of new infections and thus decrease HIV incidence.

**HIV prevalence** is the percentage of people in a population who are currently living with HIV. For example, a prevalence of 10% among people who inject drugs indicates that 10% of all people who inject drugs are living with HIV. Changes in HIV prevalence do not indicate whether the number of new infections is increasing or decreasing. Changes indicate only whether the overall proportion of people living with HIV is increasing or decreasing. HIV prevalence can increase even if there are no new cases of HIV infection; for example, people living with HIV now live longer due to effective treatment.

There are no easy-to-use valid methods for estimating HIV incidence among people who inject drugs, but feasible valid methods to estimate HIV prevalence are available. The focus in this document is on HIV prevalence data, although some tips on methods to estimate HIV incidence are also provided.

**Synthesize existing HIV prevalence data**

Monitoring HIV prevalence is usually conducted by the national unit responsible for HIV surveillance. The table shell (see Tool 1) should be used to combine all known information on the geographical distribution of HIV prevalence among people who inject drugs, by age, sex and other important subgroups. Existing data may be wrong or incomplete. The following tips may help to improve the data over time:

- Document the source of the HIV testing data and obtain copies of all protocols.
- Focus on collecting HIV prevalence trends from the same areas using the same protocol.
- Identify any gaps in the data and put into place appropriate data-collection methods to address these gaps.

**Estimate HIV incidence**

With effective antiretroviral treatment, people are living longer with HIV. This means that trends in HIV prevalence are a less useful measure of the impact of prevention programmes. HIV incidence measures are needed to track changes in the epidemic. Estimating HIV incidence is obtained primarily through prospective cohort studies; however, these studies take time and require a high degree of technical expertise and funding. In the absence of this gold standard, insights into HIV incidence can be obtained from HIV prevalence data. Three alternative approaches are listed here:

- **Tracking of HIV prevalence trends among people newly injecting drugs**: The lack of reliable laboratory measures of incidence forces programme managers to consider alternative measures of incidence. Using prevalent infections after a limited time of exposure to HIV may serve as a proxy for measuring incidence. For people who are at risk of acquiring HIV, measuring trends in prevalence among people who have recently initiated a risk-related behaviour (e.g. injecting drugs) may also serve as a proxy for incident infections.

- **Analysis of cohort data**: Complex methods are available to model HIV incidence from HIV prevalence data. These methods require expert knowledge and are outside the scope of the Guidelines.

- **Incidence by Modes of Transmission spreadsheet**: The Modes of Transmission analysis is a tool for showing the distribution of new infections by modes of transmission. Using available data on HIV prevalence, the size of the populations at risk for HIV infection and HIV-related risk behaviour, a simple spreadsheet estimates the mode of transmission of HIV infection in a single year, including the proportion of infections resulting from injecting drug use. The estimate of HIV
incidence for people who inject drugs is based on HIV prevalence data, the number of injecting partners in a 1-year period, the frequency of injecting, and the proportion of acts protected by clean needles. See Step 8 for further information on this tool.

Additional resources: Estimating HIV prevalence and incidence among people who inject drugs


1.4 What is the geographical distribution of the population? How many people inject drugs in each area?

**Products**

National map showing distribution and numbers of people who inject drugs

A national map should be created to show the number of people who inject drugs in each subnational area and the prevalence of HIV infection in those areas. Hand-drawn maps are sufficient; however, digital maps allow more types of analysis and permit more easily the inclusion of additional layers of geographical data, such as the location of service delivery sites.

**Methods**

Estimate the number of people who inject drugs

The importance of size estimates cannot be overstated. Size estimates are used to determine funding requirements, to monitor the coverage of services in relation to population needs, and to assess programme effectiveness. Methods for estimating the size of the population of people who inject drugs include:

- capture-recapture method;
- nomination method;
- census and enumeration method;
- multiplier methods;
- population survey methods;
- network scale-up method;
- extrapolation.
For the most up-to-date guidance on size estimation, refer to Guidelines on estimating the size of populations most at risk to HIV (UNAIDS and WHO, 2010).

The following tips may help with planning and conducting size estimations:

- The most important estimates are the populations in subnational areas with evidence of a large or growing population of people who inject drugs.
- Because the size of the population is dynamic, estimates should specify whether the estimate is of the number of people who inject drugs at any one point in time (cross-sectional estimate) or the number of people who inject drugs in the area over a certain period, such as 1 year. If the population is very mobile, then a cross-sectional estimate in one area may significantly underestimate the number of people that need services in that area over a 12-month period.
- Information useful for estimating the number of people who inject drugs can be taken from HIV surveillance reports and other routinely produced reports from government sectors such as law enforcement, hospitals and agriculture. For example, the age distribution of people tested as part of surveillance, arrest statistics, the number of people receiving opioid substitution therapy, the number of people admitted to emergency rooms for drug overdose, quantities of drugs seized, and estimates of the amount of drug produced or sold in the country may be used in multiplier methods to estimate the size of the population of people who inject drugs.

Map the size of the target population in each subnational area and the HIV prevalence among people who inject drugs

National maps can be developed after size estimates are made for the number of people who inject drugs in each subnational area and after HIV prevalence information has been compiled for each subnational area.

Subnational maps often provide more detail than national maps. One method for creating subnational maps is the Priorities for Local AIDS Control Efforts (PLACE) method, which uses the following approach:

1. Ask a large number of knowledgeable people from varying backgrounds in the subnational area where people who inject drugs can be reached.
2. Record the names and locations of the places. Visit and characterize the places.
3. Ask people who inject drugs at these locations about their behaviour, where they work, live and visit, and why they attend these venues.
4. Use these responses to find other areas where people who inject drugs can be reached.
5. Determine whether the venue would be suitable for outreach activities.
6. Map the locations of each place on hand-drawn maps, or use global positioning equipment and digital maps or photos. Geographical data from global positioning units can also be displayed using free Google Earth images.
Figure 8: Example of a map of a city from a PLACE study showing locations of venues with PWID and sex work

- PWID & sex work
- PWID venue
- Sex work
- Neither sex work or PWID

Figure 8 shows a sample map of a city from a PLACE study, indicating the locations of venues with people who inject drugs and sex work.

Spatial data such as population distribution and transportation networks may be added to maps and can be useful for identifying factors related to the geographical distribution of injecting drug use.

Another method for mapping the population is to map the number of people with AIDS among people who inject drugs by neighbourhood. The map shown in Figure 10, from the San Francisco Department of Public Health, shows cumulative AIDS figures among people who inject drugs, from 1981 until 2000. The map provides an insight into the areas of the city most likely to need HIV prevention.

**Data use**

Size estimates and maps are essential for programme planning, estimating the burden of disease, geographical prioritization of response, assessing coverage and evaluating effectiveness. Maps can describe the context of an epidemic and communicate information to people visually.

Estimates of the size of the population of people who inject drugs should be made for each subnational area.

**Additional resources**

*Conducting size estimates*

Operational guidelines for monitoring and evaluation of HIV programmes for people who inject drugs


Mapping people who inject drugs


Step 2: Identify and measure determinants. What are the biological determinants and sociodeterminants of HIV transmission among people who inject drugs?

**Overview**

**Rationale: Why is this step important?**

Successful HIV programmes must address the individual, community and structural factors that influence vulnerability and risk for HIV transmission in the local HIV epidemic context. Step 2 describes methods for measuring indicators to determine the local patterns of use of non-sterile injecting equipment, unprotected sex and other direct biological determinants of HIV transmission. This step also describes the underlying sociodeterminants, including policies and laws. Assessments should be conducted to identify the determinants of HIV transmission in each subnational area where there is evidence of injecting drug use. Characteristics may vary across different places.

**Objectives: What will this step help you do?**

- Measure baseline and monitor trends in the biological determinants of the HIV epidemic among people who inject drugs (i.e. outcome and impact indicators).
- Identify and monitor trends in the sociodeterminants at the individual, community and structural level that influence the vulnerability and risk for HIV transmission.

According to the causal pathway, HIV programmes will not reduce HIV transmission unless they reduce exposure to the virus or reduce transmission after exposure. Figure 10 shows ways to reduce exposure (e.g. by reducing the number of people who inject drugs) and ways to reduce HIV transmission after exposure (e.g. by using sterile injecting equipment). Also shown are other strategies to reduce contributing or underlying factors that influence risk and vulnerability for HIV transmission.
How to answer key questions

2.1 What are the biological determinants of HIV transmission among people who inject drugs? What is the extent of use of non-sterile injecting equipment, multiple partnerships and unprotected sex among people who inject drugs?

Products

Measures of the biological determinants of HIV transmission

Baseline measures of biological determinants of HIV transmission can be used to set targets and to monitor trends over time. Many indicators are used to measure biological determinants. Table 1 shows some examples of frequently used indicators. Indicators that measure change in HIV prevalence or incidence are called impact indicators (see Step 1); indicators that measure change in the biological determinants of HIV transmission are called outcome indicators.
Table 1

Outcome indicators relevant to HIV transmission among people who inject drugs

<table>
<thead>
<tr>
<th>Number&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Indicator label</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Percentage of people who inject drugs reporting the use of sterile injecting equipment the last time they injected</td>
</tr>
<tr>
<td>2.2</td>
<td>Percentage of people who inject drugs reporting the use of a condom the last time they had sexual intercourse</td>
</tr>
<tr>
<td>2.3</td>
<td>Percentage of people who inject drugs reporting symptoms of a sexually transmitted infection in the past 12 months</td>
</tr>
<tr>
<td>2.4</td>
<td>Average number of needle-sharing partners per year among people who inject drugs</td>
</tr>
<tr>
<td>2.5</td>
<td>Average number of acts of use of non-sterile injecting equipment with each injecting partner per year among people who inject drugs</td>
</tr>
<tr>
<td>2.6</td>
<td>Average percentage of injection events that involve sterile equipment use among people who inject drugs</td>
</tr>
<tr>
<td>2.8</td>
<td>Percentage of people who inject drugs injecting once per day or more</td>
</tr>
<tr>
<td>2.9</td>
<td>Average number of sexual partners per person who injects drugs</td>
</tr>
</tbody>
</table>

<sup>a</sup> This number refers to the numbering of the indicators in Annex 2

Methods

*Conduct biobehavioural surveys*

The best method for obtaining information about people who inject drugs is through a biobehavioural survey of a representative sample (UNAIDS, 2010b). A biobehavioural survey includes questions regarding demographic characteristics, risk behaviours and exposure to programmes. The survey also collects data on the HIV status of each respondent (see Box 4). Biobehavioural surveys of people who inject drugs should be conducted ideally every 2 years.
Box 4

Biobehavioural surveys

Biobehavioural surveys seek information about the following:

What are the sociodemographic characteristics of people who inject drugs?
- age and sex.
- What individual-level factors increase the vulnerability of the population?
  - mobility and homelessness;
  - history of incarceration;
  - poverty and sex work;
  - lack of education and lack of knowledge of transmission risks;
  - exposure to stigma.

What are the injecting behaviours of people who inject drugs?
- frequency of use of non-sterile injecting equipment;
- frequency of injection;
- frequency of sharing network
- type of drug used;
- age at first injection.

What are the sexual behaviours of people who inject drugs?
- frequency of sex;
- number of sexual partners;
- sexual concurrency;
- sex work;
- circumcision;
- age at first sex.

What is the prevalence of infection among the population?
- prevalence of sexually transmitted infections, including HIV;
- prevalence of viral hepatitis B and C and syphilis;
- number of people living with HIV who inject drugs and who are receiving antiretroviral treatment.

To what extent has the population accessed services?
- for each service, whether accessed in the past year and past month;
- whether tested for HIV in the past 12 months and aware of HIV status;
- whether participated in community-strengthening activities.

See Tool 9 for sample survey questions and Annex 2 for the indicators associated with each survey question.

Biobehavioural surveys are expensive and rarely available for subnational areas. Part of the M&E strategy for improving HIV prevention for people who inject drugs must be to increase funding for well-conducted surveys in areas with a large or increasing number of injecting drug users. Table 2 can be used as a checklist to assess the adequacy of biobehavioural surveys and improve the value of surveys. See also Steps 7 and 8 on methods for outcome and impact M&E.

Several protocols are available for conducting biobehavioural surveys. Some of the decisions that must be made in the design of a biobehavioural survey are included in Table 2. An example of an outcome evaluation protocol is provided in Step 7.
Table 2
Checklist of questions for assessing the usefulness of available survey data for M&E of HIV prevention programmes

<table>
<thead>
<tr>
<th>Number</th>
<th>Question</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Are survey protocols, questionnaires and data from all previous surveys available for use by the national M&amp;E unit?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Do the survey data include HIV test results that can be linked to survey respondents?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Have surveys been routinely conducted in the subnational areas with the greatest number of people who inject drugs?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Have the surveys been routinely conducted in the subnational areas suspected of having growing or new HIV epidemics among people who inject drugs?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5a</td>
<td>Is the sample size sufficient (i.e. at least 500) in each subnational area of interest?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5b</td>
<td>Of the 500 people studied, are at least 250 women?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5c</td>
<td>Of the 500 people studied, are at least 250 younger than 25 years?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6a</td>
<td>Were ethical approvals obtained for the surveys?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6b</td>
<td>Did the surveys clearly request and obtain informed consent from respondents?</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6c</td>
<td>Were incentives paid for participation?</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>7a</td>
<td>What was the method of recruitment for the surveys?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7b</td>
<td>What was the level of participation and refusal by people requested to participate?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8a</td>
<td>Were questions posed for measuring all of the recommended indicators?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8b</td>
<td>Is each numerator and each denominator for each indicator available from the survey data?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9a</td>
<td>Were results of previous surveys shared at the subnational level?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9b</td>
<td>Were results of previous surveys shared with service delivery providers?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9c</td>
<td>Were results of previous surveys shared with members of the population who inject drugs?</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Analyse service delivery data
In the absence of any survey data, information should be collected at the service delivery level about clients using the services. This information can provide information about HIV transmission. Be cautious, however, when interpreting these data, because the characteristics of people accessing services may be different from the characteristics of people who are not accessing services.
Additional resources:
Collecting a representative sample – biological determinants of injecting drug use

2.2 What are the sociodeterminants associated with HIV transmission among people who inject drugs? What individual, community and structural barriers exist that limit availability and access to prevention programmes for people who inject drugs? What individual, community and structural strengths can be leveraged for HIV prevention?

Products
Measures of sociodeterminants or contributing factors of HIV transmission
Contributing or underlying factors for HIV transmission include lack of education, lack of knowledge about HIV and AIDS, stigma attached to living with HIV, and difficulties in accessing services. Each setting is different. Understanding and tracking the most important factors that contribute indirectly to HIV transmission is critical but often overlooked. Table 3 gives some examples of indicators related to sociodeterminants at the individual level. Targets can be set and trends monitored over time.

Table 3
Indicators related to sociodeterminants for HIV transmission at the individual level

<table>
<thead>
<tr>
<th>Numbera</th>
<th>Indicator label</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.11</td>
<td>Percentage of people who inject drugs who correctly identify ways of preventing the sexual transmission of HIV and reject major misconceptions about HIV</td>
</tr>
<tr>
<td>2.12</td>
<td>Percentage of people who inject drugs who are aware of their HIV status</td>
</tr>
</tbody>
</table>

aThis number refers to the numbering of the indicators in Annex 2

Barriers that limit the use of sterile injecting equipment and condoms should be addressed. Some barriers are laws or policies that affect the entire country – for example, laws that prevent needles and syringes from being exchanged, or cultural stigma against people who inject drugs are barriers. Many barriers exist at the local level, such as lack of training by service providers in issues related to injecting drug use, law enforcement activities by the police, and how drugs are distributed. The National Commitments and Policy Instrument should be used to assess these factors. Table 4 lists 10 items adapted from this index for application to people who inject drugs. These indicators relate to the laws and policies in a country that can help or hinder HIV prevention efforts. They can reveal community engagement in addressing the HIV epidemic among people who inject drugs.
Table 4
Indicators related to sociodeterminants or contributing factors for HIV transmission at the national, community and structural level

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.13.1 Does the country have a national multisectoral strategy for HIV prevention, treatment and care among people who inject drugs that meets international standards?</td>
<td></td>
</tr>
<tr>
<td>2.13.2 Does the country have a mechanism to promote interaction between all sectors for implementing HIV programmes for people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13.3 Are people who inject drugs actively involved in HIV policy and programme implementation and M&amp;E?</td>
<td></td>
</tr>
<tr>
<td>2.13.4 Does the country have non-discrimination laws specifying protection for people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13.5 Is the country free from national laws, regulations and policies that present obstacles to effective HIV prevention, treatment and care for people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13.6 Is there a national mechanism to record, document and address cases of discrimination experienced by people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13.7 Does the country have a policy or strategy to promote information education and communication, and other preventive health interventions for people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13.8 Are programmes in place to reduce HIV-related stigma and discrimination against people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13.9 Does the country have a policy to ensure equal access for people who inject drugs to HIV prevention, treatment and care services?</td>
<td></td>
</tr>
<tr>
<td>2.13.10 Has the country identified the specific needs for HIV prevention programmes for people who inject drugs?</td>
<td></td>
</tr>
<tr>
<td>2.13 Index score (number of items = yes)</td>
<td></td>
</tr>
</tbody>
</table>

Methods
Use surveys and questionnaires, qualitative methods, and law and policy reviews
Information on barriers and strengths should be obtained using various methods, including:

- surveys and questionnaires (e.g. questions on HIV-related knowledge or on stigma related to drug addiction can be included in biobehavioural surveys);
- qualitative methods, including:
  - focus group discussions (e.g. on discrimination experienced by people living with HIV in the local community);
  - individual in-depth interviews (e.g. on personal barriers to accessing HIV-related services);
  - observations (e.g. observing the attitudes of health-care providers when dealing with people who inject drugs);
  - rapid assessments (e.g. the Rapid Assessment and Response method described in Step 1);
- law and policy reviews (e.g. on criminalization of drug addiction).

The following questions are helpful in identifying sociodeterminants:
- What policies or factors influence the use of needle–syringe programmes by people who inject drugs?
- Where are services available? Are they used? Why or why not?
- What factors are associated with high and low use of services?
- What policies or factors influence first-time drug injections?
- What policies or factors influence patterns of risk behaviour?
- What is the organizational structure of the drug production and delivery? How does this influence the behaviour of people who inject drugs?
- Which characteristics of the physical locations and social drug-using networks influence negative patterns of drug use and other risky behaviours?
- How do the beliefs and value systems of the community in which people who inject drugs live influence the development of health policy and interventions?
- Is lack of knowledge a barrier to using sterile injecting equipment?
- How does the individual’s degree of dependence or severity of withdrawal syndrome influence his or her patterns of drug use and risk behaviour?
- How does the individual’s use of multiple drugs, including alcohol, influence his or her patterns of drug use and risk behaviour?
- How does the individual’s knowledge or lack of knowledge about his or her HIV sero-status influence his or her patterns of drug use and risk behaviour?
- How does the individual’s mental health influence his or her patterns of drug use and risky behaviour?

**Data use**

Monitoring and in-depth analysis of barriers to effective service delivery helps in the design of interventions to address these barriers and track whether they succeed in changing the targeted barriers. Likewise, identifying and tracking individual, community and structural strengths can be used to increase the availability of, access to and effectiveness of HIV prevention services.

**Additional resources: Identifying sociodeterminants**


Step 3: Know your response and set targets. What is the current programmatic response, and what are the targets?

Overview

Rationale: Why is this step important?

In this step, essential indicators at the national and subnational level are defined. Targets are set for each coverage, outcome and impact indicator, thus monitoring performance. These targets are based on the current response, including the availability of services and the baseline indicator values.

Objectives: What will this step help you do?

- Define the package of services that should be provided for the national and subnational response.
- Map the availability of each service in the package of services in each subnational area.
- Specify coverage, outcome and impact indicator targets nationally and in each subnational area.

The comprehensive package of recommended interventions is discussed under the heading Need for a comprehensive approach to addressing HIV among people who inject drugs.

See also the Target setting guide.

How to answer key questions

3.1 Based on the epidemic among people who inject drugs and analysis of determinants, what combination of services and activities is needed to prevent HIV transmission?

Products

Define national package of services

National responses to the HIV epidemic vary by country. The following comprehensive package of interventions is based on international normative guidance and policy documents for HIV prevention for people who inject drugs and includes:

- needle–syringe programmes;
- opioid substitution therapy and other drug dependence treatment;
- HIV testing and counselling;
- antiretroviral treatment;
- targeted information, education and communication for people who inject drugs and their sexual partners;
- prevention and treatment of sexually transmitted infections;
- condom-promotion programmes for people who inject drugs and their sexual partners;
- vaccination, diagnosis and treatment of viral hepatitis;
- prevention, diagnosis and treatment of TB.

The maximum benefit is gained by implementing all nine parts of the comprehensive package together; thus, it is important to conduct ongoing M&E for each of these interventions. It is recognized, however, that countries are at different stages of establishing a comprehensive response, and that limitations may
exist in monitoring and evaluating all components of the package. It is advised that at least needle–
syringe programmes, opioid substitution therapy, HIV testing and counselling and antiretroviral
treatment be monitored as a minimum requirement.

As some countries will not be able to provide all nine services, the national minimum package of
services to be provided to each client should be agreed and clearly defined at the national level. This is
important for planning service delivery and also for monitoring purposes such as data collection and
reporting on who should be counted as “reached with HIV prevention package”.

In addition, structural and community interventions include:

- addressing legal barriers;
- training and sensitization of service providers;
- community mobilization;
- establishing safe spots to ensure that members of the most-at-risk population have a place staffed
  by supportive individuals where they can access information about services without fear of being
  stigmatized.

Methods

Conduct strategic response planning

It is necessary to specify the national package of services, the structural reforms and the community
interventions. Describe each service or intervention adopted as part of the national response,
including: (1) how the service or intervention is defined; (2) the frequency with which the service or
intervention should be provided or implemented; and (3) what constitutes having received the service
or intervention. See under the heading Need for a comprehensive approach to addressing HIV among
people who inject drugs, for information on the programme impact pathway for the national and subna-
tional level as an important tool for planning, implementation and M&E of the overall HIV response
and of the impact of this response on the HIV epidemic among people who inject drugs.

Figure 11 Step 3: Know your response and set targets

<table>
<thead>
<tr>
<th>Key questions</th>
<th>Methods</th>
<th>Products</th>
<th>Data use</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Based on the epidemic among the population, what services are needed in response?</td>
<td>Conduct strategic response planning</td>
<td>Defined national package of services</td>
<td>List of services in the national package are used to define coverage indicators</td>
</tr>
<tr>
<td>3.2 For each sub-national area: What services are currently available? What contributing factors are being addressed?</td>
<td>Map service availability through stakeholders meetings</td>
<td>Service availability maps</td>
<td>Service availability maps are used to identify gaps in services</td>
</tr>
<tr>
<td>3.3 Based on the assessment, what are the 2-year targets for impact, outcome and coverage indicators in each sub-national area?</td>
<td>Use target-setting methods</td>
<td>Specific targets for impact, outcome and coverage indicators</td>
<td>Targets are used to assess programme performance</td>
</tr>
</tbody>
</table>
Data use

The definition of the national minimum package of services is used to determine coverage indicators for each individual service provided and for the package of services when reporting on the coverage indicator “reached with HIV prevention package”.

3.2 What services are currently provided in each subnational area? What other activities are being undertaken to address factors that contribute to the HIV epidemic?

Products

Service availability map

Figure 12 shows a sample map of existing service delivery sites for groups at risk of acquiring HIV, including people who inject drugs, in the Republic of Moldova.

Figure 12: Example of service delivery sites for at-risk groups in Moldova


Methods

Map service availability

Service availability can be mapped simply by bringing together knowledgeable people to review available information on the services provided in the country. The WHO Health Statistics and Health Information Systems Web site (see Additional resources) has a full protocol for prevention service availability. This protocol can be used to map all available HIV prevention services, including services for populations most at risk, the general population and youths. The protocol includes forms to collect information at health facilities.
As access to geographical information systems becomes less expensive and more user-friendly, mapping facilities and services becomes easier. WHO supports a mapping interface called Health Mapper, which can be used at the national and local level to map services. The advantages of using Health Mapper are that many health services are already mapped for each country, and other useful information is already available in these maps. Countries can build on these maps.

**Data use**

Using service availability maps in accordance with defined needs will assist in the setting of realistic targets for service delivery in the future. In addition, this information can be used to assess the geographical availability of each service in each subnational area (see Table 5), which allows for readjustment where needed.

### Table 5

**Indicators to assess geographical coverage of services**

<table>
<thead>
<tr>
<th>Number</th>
<th>Indicator label</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.18</td>
<td>Is each component of the package of services for people who inject drugs available in the area (yes/no for each component)?</td>
</tr>
<tr>
<td>3.19</td>
<td>Number of sites offering a component of the basic package for people who inject drugs per 1000 people who inject drugs</td>
</tr>
</tbody>
</table>

*This number refers to the numbering of the indicators in Annex 2*

**Additional resources: Service availability mapping**


*District Health Information Software* (http://dhis2.org/).


### 3.3 What are the current baseline and the 2-year targets for changes in coverage, outcome and impact indicators?

**Products**

*Targets for impact, outcome and coverage indicators*

Target-setting is essential for high-quality monitoring and evaluation. Targets should reflect programme strategies and be based on what can be achieved in a specific time period. Targets should be set for impact, outcome and coverage indicators at the national level and for each subnational area where needed. Table 6 shows some examples of targets for impact, outcome and coverage indicators.
Table 6
Examples of targets for impact, outcome and coverage indicators

<table>
<thead>
<tr>
<th>Indicator type</th>
<th>Indicator</th>
<th>2010 (baseline)</th>
<th>2012</th>
<th>2014</th>
<th>Change from baseline</th>
<th>Target</th>
<th>Change from baseline</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact</td>
<td>1.1 HIV prevalence among people who inject drugs</td>
<td>30%</td>
<td>–5%</td>
<td>28.5%</td>
<td>–10%</td>
<td>27%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome</td>
<td>2.1 Percentage of people who inject drugs who report the use of sterile injecting equipment the last time they injected</td>
<td>60%</td>
<td>+10%</td>
<td>66%</td>
<td>+20%</td>
<td>72%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.12 Percentage of people who inject drugs who correctly identify ways of preventing sexual transmission of HIV and who reject major misconceptions about HIV</td>
<td>60%</td>
<td>+20%</td>
<td>72%</td>
<td>+40%</td>
<td>84%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coverage</td>
<td>3.4 Percentage of people who inject drugs reached by information, education and communication programme in past 12 months</td>
<td>50%</td>
<td>+20%</td>
<td>60%</td>
<td>+40%</td>
<td>70%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.7 Percentage of people who inject drugs regularly reached by needle–syringe programmes (at least once per month in past 12 months)</td>
<td>40%</td>
<td>+20%</td>
<td>48%</td>
<td>+40%</td>
<td>56%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Numbers are intended to be illustrative and are not a recommendation.

Methods
Use target-setting methods
Target-setting is a collaborative process requiring input from a range of stakeholders. This ensures targets are set using the best available evidence, are agreed upon and are understood.

The following tips for target-setting may be useful (see also WHO, 2009b):

- Targets should reflect programme strategies that tailor the response to the epidemic.
- Targets should be set for impact, outcome and coverage indicators at the national level and for each subnational area.
- Targets should be based on baseline measurements of key indicators selected. Use the indicators described in Annex 2 as these are all measurable. If baseline data are not available, use the best possible judgement for defining targets.
Document the source of the data used for baseline estimates. Many of the indicators are based on biobehavioural surveys. These should be conducted routinely every 2 years. Other indicators are based on programme data.

For each indicator, set a 2-year target based on what change from the baseline measurement can be achieved over the next 2 years with available funding and resources.

Targets should also be set for protocol development, programme documentation, M&E system-strengthening, data quality, and structural and community interventions.

There is no universal formula for setting targets. There is limited evidence to assist in defining minimum levels of coverage or thresholds required for services to achieve a desired impact. Countless factors can affect the extent of HIV risk behaviours and levels of HIV transmission among people who inject drugs. These factors influence the minimum level of coverage required in a given context. Useful targets can be set by acknowledging that greater levels of coverage are superior to lower levels of coverage. Setting targets for the first time is difficult, since there is less experience with understanding what can be accomplished over time. Table 7 describes methods for setting targets. Further detailed guidance is given in the Target setting guide.

### Table 7

#### Overview of target-setting methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 years to 80%</td>
<td>Identify the baseline indicator. For example, with a baseline of 20%, determine the gap between 20% and the target of 80%. If it takes 10 years to get to 80% from 20%, how far can you get in 2 years? The programme should aim to improve 6% each year, or 12% in 2 years. At this rate, the target of 80% will be achieved in 10 years. A target of 100% is rarely reached, and targets of 80% are more feasible. Change does not occur quickly. A 10-year plan is reasonable for hard-to-change behaviours.</td>
</tr>
<tr>
<td>x% increase</td>
<td>For each indicator, increase the target by 20% from baseline. For example, if the target should increase proportionally by 20% and the baseline is 40%, then the target is 48% (20% of 40% = 8%).</td>
</tr>
<tr>
<td>Absolute increase</td>
<td>For each indicator, an absolute increase in the baseline of x amount is set as a target. For example, if the target should increase by an absolute 20% and the baseline is 40%, then the target is 60% (40% + 20% = 60%). This type of target-setting is often difficult to rationalize.</td>
</tr>
<tr>
<td>Expert opinion or consensus</td>
<td>Some behaviours are harder to change, and take more time to modify, than others. New programmes may require a longer time to gain the cooperation of the community and yield results. Many factors can affect the achievement of targets. In this method, local people, including members of the target population, assess these factors and set reasonable targets based on their insight and knowledge.</td>
</tr>
<tr>
<td>Trends</td>
<td>Countries and subnational areas that have a strong programme can review trends in indicators and extend the trend line of each indicator (unless the trend is going in the wrong direction).</td>
</tr>
<tr>
<td>Better than the rest</td>
<td>If baseline targets are known for several priority prevention areas, set targets higher than any area has achieved. The goal is to improve beyond what the best area has achieved. This method is not appropriate in some settings, but it may encourage healthy competition.</td>
</tr>
</tbody>
</table>
The worksheet (see Tool 4) in the Tools section provides a template for documenting baseline and follow-up measures of impact, outcome and coverage indicators, the target for each indicator, and whether the target was met. The worksheet should be completed at the national level and in each subnational area. Additional indicators can be included.

**Additional resources: Target-setting for programmes for people who inject drugs**


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**Steps 4–6: Overview of input, quality and output monitoring and process evaluation**

By the end of Step 3, targets have been set to monitor the national and subnational response and results. In Steps 4–6, monitoring determines whether the services and interventions developed as part of the planned national response are being implemented on time, with sufficient quality, and at the scale required to achieve the set targets. Steps 4–6 collect data to answer the questions “What interventions and services are we implementing?” and “Are we doing them right?”

Input, quality and output monitoring are linked closely to process evaluation. Typically, process evaluation collects more detailed information about the way the programme is implemented and received by the target population than can be collected through routine monitoring. Process evaluation can build upon the monitoring data and collect additional information on access to services, whether the services reach the intended population, how the services are delivered, client satisfaction and perceptions about their needs, and management practices. This detailed information is collected at the service delivery sites for making timely corrections in service provision. Hence, the subnational and national levels will focus on the routine monitoring data to assess implementation progress. Often, the subnational and national levels will conduct spot checks and supportive supervision visits to a sample of the service delivery sites. Given this division of labour, Steps 4–6 focus on routine monitoring data relevant at the national and subnational level.
Step 4: Input monitoring. What resources are needed to reach the subnational and national targets?

Overview

Rationale: Why is this step important?

This step identifies whether there are sufficient funds and other resources available to implement the national and subnational response to the epidemic. The approach determines what is an appropriate programmatic response, before assessing whether the resources are adequate. Information from this step can be used to apply for additional funding and other resources. If additional resources are not provided, then information collected in this step can be used to decide how to scale back programme implementation and readjust targets.

Objectives: What will this step help you do?

- Monitor gaps in funds and other resources (i.e. inputs) to justify additional resources to achieve targets.

How to answer key questions

4.1 What is the gap between the funds needed to meet targets and the amount available? What is the gap between other resources needed to meet targets and the resources available?
Products

Resource analysis and monitoring data

Table 8 gives an example of the types of data needed to determine resource gaps for implementation of a planned programme (e.g. needle–syringe programme) and to monitor the level of resources throughout programme implementation.

Table 8
Example of funding and other resource inputs for a national needle–syringe programme

<table>
<thead>
<tr>
<th>Service</th>
<th>Level</th>
<th>Funds needed</th>
<th>Funding source</th>
<th>Funding gap</th>
<th>Monitoring funding at national level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle–syringe programme</td>
<td>National</td>
<td>100 000</td>
<td>100 000</td>
<td>0</td>
<td>100 000</td>
</tr>
<tr>
<td>Other resource inputs</td>
<td>Needed</td>
<td>Available</td>
<td>Gap</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human resources (staff, volunteers, consultants)</td>
<td>20</td>
<td>10</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment (computers)</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commodities (needles and syringes)</td>
<td>10 000</td>
<td>5000</td>
<td>5000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best practices materials</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: numbers are intended to be illustrative and are not a recommendation.

Methods

Use the Goals Model for financial resource analysis

The gap in funds is the difference between the funds needed and the funds received. Estimating the funds needed to meet targets can be difficult if the services were not previously provided.

Tools for cost analysis and resource planning are available. For example, the Goals Model estimates the cost of HIV interventions based on the desired level of coverage. Costing worksheets for computer spreadsheet programmes are also available.

Use a spreadsheet tool for financial resource analysis

The spreadsheet shown in Table 9 shows the financial resource information needed to implement services in each subnational area (see also Tool 5). This should include the source of the funds and the level of funds already expended to determine whether funds are sufficient for sustained programme implementation.
Table 9
Example spreadsheet to monitor funding at the national and subnational level

<table>
<thead>
<tr>
<th>Service</th>
<th>Level</th>
<th>Funds needed</th>
<th>Input source</th>
<th>Funding gap</th>
<th>Monitoring funding at national level and in each subnational area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Gov't</td>
<td>Donor 1</td>
<td>Total US$</td>
<td>Funds expended US$</td>
</tr>
<tr>
<td>Needle-syringe programme</td>
<td>National</td>
<td>100 000 US$</td>
<td>100 000 US$</td>
<td>100 000 US$</td>
<td>60 000 US$</td>
</tr>
<tr>
<td></td>
<td>Sub-national area 1</td>
<td>20 000 US$</td>
<td>10 000 US$</td>
<td>10 000 US$</td>
<td>10 000 US$</td>
</tr>
<tr>
<td></td>
<td>Subnational area 2</td>
<td>80 000 US$</td>
<td>30 000 US$</td>
<td>60 000 US$</td>
<td>20 000 US$</td>
</tr>
</tbody>
</table>

Note: numbers are intended to be illustrative and are not a recommendation.

The National AIDS Spending Assessment is a resource-tracking matrix that monitors the annual flow of funds as countries move towards universal access to prevention, treatment and care services (see Additional resources).

**Conduct other resource needs analysis**

The gap in inputs other than funding is the difference between the inputs needed and the inputs available. The example in Table 10 can be expanded to track specific categories of human resources, commodities and equipment (see Figure 14).

**Figure 14: Inputs and outputs**

![Figure 14: Inputs and outputs](image-url)
Table 10
Example spreadsheet to monitor inputs other than funding at the national and subnational level

<table>
<thead>
<tr>
<th>Input</th>
<th>Needed</th>
<th>Available</th>
<th>Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human resources (staff, volunteers, consultants)</td>
<td>20</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Equipment (computers)</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Commodities (needles, syringes)</td>
<td>10 000</td>
<td>5000</td>
<td>5000</td>
</tr>
<tr>
<td>Best practice materials</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td><strong>Subnational area 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human resources (staff, volunteers, consultants)</td>
<td>20</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Equipment (computers)</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Commodities (needles, syringes)</td>
<td>10 000</td>
<td>5000</td>
<td>5000</td>
</tr>
<tr>
<td>Best practice materials</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td><strong>Subnational area 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human resources (staff, volunteers, consultants)</td>
<td>40</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Equipment (computers)</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Commodities (needles, syringes)</td>
<td>30 000</td>
<td>20 000</td>
<td>10 000</td>
</tr>
<tr>
<td>Best practice materials</td>
<td>50</td>
<td>40</td>
<td>10</td>
</tr>
</tbody>
</table>

Note: numbers are intended to be illustrative and are not a recommendation.

Data use
Information on resource gaps can be used to justify a request for additional resources to achieve the set targets, or to modify the programme implementation (and associated targets) in line with available resources if additional resources cannot be obtained.

Additional resources: Resource planning and allocation


Step 5: Quality monitoring. What interventions and services are actually implemented? With what quality?

Overview

Rationale: Why is this step important?

Quality has different meanings for different stakeholders, such as governments, service providers, and individuals who request or are advised to have a given intervention. Some stakeholders are more concerned about the performance of the system, some about the quality of the care delivered, and some about the quality of the care received. In reality, all three perspectives are for ensuring quality:

- performance of the system;
- professional standards;
- client satisfaction.

The concepts of quality improvement apply equally to all levels of the health system. At the national level, the vision for improving quality starts with planning and defining national standards. The subnational level takes on the national vision, using routine monitoring data to support facility efforts in monitoring, improving and evaluating quality.

Implementing high-quality services according to plan is a challenge. Programme effectiveness suffers if, for example, people do not feel welcome in the service, the service is not provided in an accessible setting or at a convenient time, supplies run out, or providers are not well trained. There may be high staff turnover among service delivery providers, requiring frequent training and retraining. This step provides methods for quality improvement.

Objectives: What will this step help you do?

- Assess whether the quality of services provided is according to national standards so timely corrections can be made.

How to answer key questions

5.1 Are national quality standards available? Are they updated regularly?

Products

National quality standards

National quality standards provide guidance for implementing high-quality services. They also standardize quality assessments to identify any weaknesses that need correction. Universal standards apply to all programmes (see Box 5).

Methods

Hold a consensus meeting to establish national quality standards

Quality standards need to be created at the national level, with input from service providers and the population served. An accreditation system for service sites or certification for service providers ensures that the quality of services is regularly assessed and approved according to the national quality standards. This also provides transparency to service users.
Box 5
Universal quality standards that should be applied across all services

**Standard for involving people who inject drugs:**
- ensure the populations identified for targeted services are included in the needs assessment, planning, delivery and evaluation of the services.

**Standards for clients’ rights:**
- ensure clients are fully informed of the nature and content of the services and the risks and benefits to be expected;
- ensure confidentiality and privacy of clients are maintained at all times;
- ensure adherence to human rights and removal of legal barriers to access services;
- ensure access to medical and legal assistance for people who inject drugs who experience sexual coercion or violence.

**Standards for providing a comprehensive package of services to people who inject drugs:**
- ensure awareness and easy access to all components of the package of services;
- ensure protocols for delivery of each component of the comprehensive package are updated periodically, and disseminated to and adhered to by all service providers.

**Standards for staffing:**
- ensure staff members receive regular supervision by senior staff to maintain quality of service delivery;
- ensure service providers are trained and sensitized to not discriminate against people who inject drugs.

**Standards for the availability and accessibility of services:**
- ensure services are accessible to all potential clients, irrespective of age, ethnicity, sexual orientation, citizenship, religion, employment status, health insurance status or substance use status;
- ensure services are easily accessible with regard to location, transportation options, travelling time and cost;
- ensure services are equitable and non-discriminatory – there should be no exclusion criteria, except on medical grounds (e.g. opioid substitution therapy should not be limited to people who inject drugs and are living with HIV or who have failed on other drug dependence treatment);
- ensure availability of safe virtual and physical spaces (e.g. telephone hotlines, drop-in centres) for people who inject drugs to obtain information and referrals for prevention, treatment and care services.

**Data use**
National quality standards guide the implementation of high-quality services that are consistent across all service providers. In addition, national quality standards should be used to monitor key information to assess whether the services are implemented as set forth in the quality standards.

**Additional resources: Quality standards**


5.2 What is the quality of each service being provided?

**Products**

*Data on service quality*

Quality assessments should include the measurement of key indicators. Table 11 gives some examples of service quality indicators.

Table 11

<table>
<thead>
<tr>
<th>Numbera</th>
<th>Quality indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Percentage of programme sites adhering to WHO and UNFPA guidelines</td>
</tr>
<tr>
<td>5.2</td>
<td>Percentage of occasions when clients access a needle–syringe programme and receive information, education and communication</td>
</tr>
<tr>
<td>5.3</td>
<td>Percentage of occasions when clients access a needle–syringe programme and receive condoms</td>
</tr>
<tr>
<td>5.4</td>
<td>Percentage of patients on opioid substitution therapy who are receiving recommended maintenance dose</td>
</tr>
<tr>
<td>5.5</td>
<td>Percentage of patients on opioid substitution therapy who have been on opioid substitution therapy continuously for past 12 months</td>
</tr>
<tr>
<td>5.6</td>
<td>Average duration of opioid substitution therapy</td>
</tr>
<tr>
<td>5.7</td>
<td>Average maintenance dose of opioid substitution therapy</td>
</tr>
<tr>
<td>5.8</td>
<td>Number of individuals in compulsory drug treatment</td>
</tr>
<tr>
<td>5.9</td>
<td>Percentage of people who inject drugs and are diagnosed with a sexually transmitted infection who have received treatment</td>
</tr>
</tbody>
</table>

aThis number refers to the numbering of the indicators in Annex 2.

**Methods**

*Conduct quality assessments*

A checklist of quality standards for each service and for the M&E system is provided in the Tools section (see Tool 6). This checklist was developed for the Guidelines as no simple checklist already existed. A section of the full quality checklist is shown in Box 6. Quality standards should be disseminated to subnational levels and to all service providers, and a schedule for regular quality assessments should be established and implemented.
Quality checklist (short version)

For all services: The five “A”s approach

- adherence to national standards;
- availability of service;
- accessibility of service;
- acceptability of service;
- attitudes of service delivery providers towards clients are positive.

When providing services:

- there is a system in place to ensure no stock-outs occur;
- a unique identifier code or other system exists to count the number of unique clients rather than the number of contacts;
- there is an established referral system, including a follow-up mechanism;
- information, education and communication are provided;
- a risk assessment is conducted;
- condoms are provided for sexually active people who inject drugs.

For each separate service

Needle–syringe programmes:

- clients receive information, education and communication when accessing needle–syringe programmes;
- clients receive condoms when accessing needle–syringe programmes.

Opioid substitution therapy and other drug-dependence treatment:

- clients on opioid substitution therapy receive the recommended maintenance dose of 60mg methadone per day or 12mg buprenorphine per day;
- clients in opioid substitution therapy return regularly to receive services;
- clients are in voluntary treatment.

Prevention and treatment of sexually transmitted infections:

- people diagnosed with sexually transmitted infections receive appropriate treatment;
- case management of sexually transmitted infections is delivered with the quality specified in the national guidelines.

Provision of condoms and lubricants:

- there is a national policy on social marketing of condoms;
- condoms are consistently available within the country;
- condoms are available to consumers at the right time, the right place and the right price;
- all condoms are of reliable quality at the time they reach the consumer;
- condoms are provided in a respectful manner, with adequate information on how to use a condom;
- lubricants are provided at the same time as condoms.

Antiretroviral treatment:

- injecting drug use does not exclude a person from accessing antiretroviral treatment services;
- there is a protocol addressing the special treatment needs of people who inject drugs who are eligible for antiretroviral treatment.
Data use

Quality assessments should be used to identify strengths and weaknesses in the service provision. The findings must be followed up in terms of timely implementation of improvements. A substandard service is not acceptable. Quality assessment findings should be communicated to service delivery providers to take action for improvement. One strategy is to bring together service delivery providers to hear the results of different quality assessments and to develop an approach to address the weaknesses identified. Subsequently, service delivery providers can execute the plan and collect new data to assess whether the actions taken were adequate. The initial group of providers can then be brought back together to present the results, and successful strategies can be shared to be used elsewhere.

The following points should also be noted:

- Internal audit results should be used to assess the quality of services provided and to improve performance.
- Meetings with members of the target population can increase the acceptability of services.
- Staff morale should increase as the quality of services increases.
- Service delivery providers with problems or successes in quality can help other providers by sharing their problems and solutions.

Additional resources


Figure 14b Step 5: Quality Monitoring
Step 6: Output monitoring, including coverage. Are the intended outputs achieved? What proportion of the population in need received services?

Overview

Rationale: Why is this step important?

High-quality services that reach only a few people in the target population cannot be expected to change the direction of the HIV epidemic in that population. High coverage of the population (i.e. a high proportion of the population reached with services) is needed. Hence, calculation of coverage is one of the most important components of monitoring performance.

Objectives: What does this step help you do?

- Create a national definition of “reached with service or package of services”.
- Monitor outputs across service providers and avoid double-counting of clients.
- Monitor geographical coverage and calculate population coverage – the proportion of the population reached by each service and by a package of recommended services.

Figure 15 (19) Step 6: Output monitoring, including coverage
How to answer key questions

6.1 What is the operational definition of “a person reached with a service or package of services”?

Products
Definition of what is meant by “reached with a service or a package of services”
To be able to monitor services correctly, criteria must be defined for counting whether a person has been “reached with a specific service”. For example, a client is considered:

- “reached by a needle–syringe programme” when he or she has accessed a needle–syringe programme at least once per month in the past 12 months;
- “reached by opioid substitution therapy” when he or she has received methadone continuously for at least 6 months in the recommended maintenance dose per day (60–120mg methadone per day).

In addition, criteria need to be defined for counting whether a person has been “reached with a package of services” as per the national definition. For example, a client is considered “reached with an HIV prevention package” when he or she has received all of the following services in the past month:

- provided with clean needles and syringes;
- provided with condoms;
- provided with an information brochure about HIV and how to protect oneself from HIV infection.

Beginning with 2012 country reporting on the Global AIDS Indicators (formerly UNGASS), a person who injects drugs is considered to be reached with an HIV prevention programme based on the number of syringes distributed per person who injects drugs per year by needle–syringe programmes. This is a new indicator and replaces the previous UNGASS indicator 9.

Methods
Organize a national forum to agree a national definition of “reached with a service or package of services”
A national forum including representatives from governmental, nongovernmental and international organizations should discuss and agree on a standardized definition of what is meant by “reached” for each service in the national package of services and for the overall package of services (see Table 12).
## Table 12

Definition of “person reached with a service” for each service in a comprehensive package of services for people who inject drugs

<table>
<thead>
<tr>
<th>Service</th>
<th>Definition of “person reached with the service”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle–syringe programme</td>
<td>Accessed a needle–syringe programme at least once per month in past 12 months</td>
</tr>
<tr>
<td>Opioid substitution therapy or other drug-dependence treatment</td>
<td>Received methadone or buprenorphine continuously in the recommended maintenance dose per day (60–120mg methadone or 12–24mg buprenorphine) for at least 6 months</td>
</tr>
<tr>
<td>HIV testing and counselling</td>
<td>Received an HIV test and counselling (including provision of the test result) in the past 12 months and was referred to treatment if tested positive for HIV</td>
</tr>
<tr>
<td>Antiretroviral treatment</td>
<td>Enrolled in an antiretroviral treatment programme</td>
</tr>
<tr>
<td>Targeted information, education and communication for people who inject drugs and their sexual partners</td>
<td>Received information about the risk of HIV transmission via use of non-sterile injecting equipment and unprotected sex, through peer education or counselling at least once in past 12 months</td>
</tr>
<tr>
<td>Prevention and treatment of sexually transmitted infections</td>
<td>Screened or tested for sexually transmitted infections at least once in past 12 months, and treated if needed (the infection must be specified, e.g. gonorrhoea, syphilis, chlamydia, trichomonas)</td>
</tr>
<tr>
<td>Condom promotion programmes for people who inject drugs and their sexual partners</td>
<td>Accessed free condoms from a programme targeting people who inject drugs and received instructions on correct condom use at least once during past 12 months</td>
</tr>
<tr>
<td>Vaccination, diagnosis and treatment of viral hepatitis</td>
<td>Vaccinated for hepatitis B during past 12 months, Tested for hepatitis B and referred for treatment if needed during past 12 months, Diagnosed with and completed treatment for hepatitis B during past 12 months, Tested for hepatitis C and referred for treatment if needed during past 12 months, Diagnosed with and completed treatment for hepatitis C during past 12 months</td>
</tr>
<tr>
<td>Prevention, diagnosis and treatment of TB</td>
<td>Screened or tested for TB during past 12 months and referred for treatment if neededCompleted treatment for TB during the past 12 months</td>
</tr>
</tbody>
</table>

Definitions should be carefully documented and shared with all service providers to ensure consistency in data collection by different service providers over time. Definitions of “reached” may also include a component that measures the quality of the service. Although this information is essential, including
quality criteria may make the output indicator much harder to collect on an ongoing basis. Other available methods allow for a regular in-depth assessment of service quality, which may be more appropriate (see Step 5). Hence, for standardized reporting and aggregating data across service providers and subnational areas, the definitions of “reached” should be focused on the use of the services and the frequency or intensity of service use.

**Data use**

To be able to monitor services correctly, criteria need to be defined for counting whether a person has been “reached” with a specific service. For example, a person is considered “reached with an HIV testing and counselling programme” when he or she has been counselled and, unless already known to be living with HIV, has been tested for HIV in the past 12 months and knows the results of the test.

In addition, criteria should be defined for counting whether a person has been “reached with a package of services” as per the national definition.

The national definition of a “person reached” with a specific service or with a national package of services is used to standardize data collection.

6.2 What outputs will be monitored at the subnational level? How will service delivery providers avoid double-counting?

**Products**

**Output indicators**

An output is an immediate result of the service or intervention that can be counted. Counting outputs provides evidence that activities occurred. Outputs monitored are the number of people reached with services, the number of services provided, and the number of commodities distributed. At the subnational level, frequently monitored outputs include:

- the number of people reached with a service or package of services;
- the number of people who inject drugs who are reached with a needle–syringe programme;
- the number of people who inject drugs who are on opioid substitution therapy;
- the number of people who inject drugs who are receiving antiretroviral treatment;
- the number of services provided;
- the number of HIV testing and counselling sessions provided;
- the number of commodities distributed;
- the number of needles and syringes distributed in the subnational area;
- the number of condoms distributed in the subnational area;
- the number of people trained;
- the number of health-care providers trained in issues related to injecting drug use, including how to counsel people who inject drugs and detection and treatment of sexually transmitted infections.
Outputs that are less frequently monitored but are useful to monitor barriers to access of services include:

- the number of meetings held with officials to address legal barriers for people who inject drugs to access services;
- the number of physical safe spots organized in the community for people who inject drugs.

**Strategy to avoid double-counting**

A system to avoid double-counting is needed to identify how many different individuals from the target population were reached with a service, rather than the number of contacts the programme made with the population. Depending on the advancement of the data monitoring system, different strategies are available to avoid double-counting of an individual or to identify how many different individuals were reached with the service.

**Standardized forms for data collection, reporting and aggregating**

The standardized forms commonly used are:

- encounter forms (see Tools 7 and 8);
- referral forms (see Tool 13);
- aggregation forms.

**Methods**

**Define output indicators**

National and subnational levels focus on selected coverage, outcome and impact indicators. A few good output indicators should also be monitored in subnational areas. Table 13 lists key requirements for specifying and monitoring output indicators.
### Table 13

**Requirements for specifying and monitoring output indicators**

<table>
<thead>
<tr>
<th>Requirements for a good output indicator</th>
<th>Clarifications/examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Fully specified indicator reference sheet</td>
<td>This should include the following information: indicator definition; rationale or purpose for the indicator; numerator; denominator (if applicable); how to calculate the indicator; measurement tool; method of measurement; data-collection frequency; how to interpret indicator data; strengths and limitations of the indicator; references to sources for further information.</td>
</tr>
<tr>
<td>2  Well-defined activity that can be counted</td>
<td>For example, number of people reached with a service or package of services, or number of commodities (condoms or needles/syringes) distributed, or number of people trained</td>
</tr>
<tr>
<td>3  Time period during which activity occurred</td>
<td>For example, number of condoms distributed each calendar month, or number of people reached by a needle–syringe programme in past month</td>
</tr>
<tr>
<td>4  For output indicators that measure the number of people “reached with a service”, an operational definition of what it means to be “reached”</td>
<td>For example, number of people who received at least one free condom with instructions on its use</td>
</tr>
<tr>
<td>5  For output indicators that measure the number of people “reached with a package of services”, an operational definition of the content of the package</td>
<td>For example, number of people reached by: needle–syringe programme; and condom promotion programme; and targeted information, education and communication; and HIV testing and counselling.</td>
</tr>
<tr>
<td>6  The output indicator meets the indicator standards</td>
<td>The indicator meets each of the following standards: Standard 1: Is needed and useful Standard 2: Has technical merit Standard 3: Is fully defined Standard 4: It is feasible to collect and analyse data Standard 5: Has been field tested or used in practice</td>
</tr>
<tr>
<td>7  Standardized data collection form to collect indicator data</td>
<td>Encounter form for recording which services were provided to the client (see Tools 7 and 8)</td>
</tr>
<tr>
<td>8  Baseline measurement of the indicator and a realistic target</td>
<td>For example: Baseline in 2009 – 60,000 condoms distributed to 500 clients (10 condoms per client per month); target for 2010 – 72,000 condoms to be distributed to 600 clients (with same assumption of 10 condoms per client per month)</td>
</tr>
</tbody>
</table>
Identify a strategy to avoid double-counting

Double-counting arises when service delivery providers know the number of contacts with the target population but do not know how many unique individuals have been contacted. Increasingly, funders want to know not only how many contacts were made with the population but also how many different individuals have been contacted.

Depending on the data monitoring system, each service delivery provider must determine what method will be used to avoid double-counting of individuals or to translate the number of contacts with the population into the number of unique individuals reached with a service. Figure 16 summarizes three different strategies to be used when reporting on the number of individual clients reached with a service.

Service delivery providers who use unique identifier codes for clients can track an individual client’s participation in the programme. They can also track the services each client receives and determine whether referrals to services have been followed up. Unique identifier codes can provide accurate information about the number of clients reached with services and the number of contacts made with each client. In order to use a unique identifier code, the service delivery provider must develop a data storage system that protects the privacy of clients; for example, government-issued identification numbers or other identifiers that are easily linked to the client should not be used. An example of a “safe” unique identifier code developed by Population Services International is a seven-digit code composed of:

- the first two letters of the client’s mother’s first name;
- the first two letters of the client’s father’s first name;
- the client’s sex (denoted by the letter M or F, or a number); and
- the last two digits of the client’s year of birth.

Develop standardized forms for data collection, reporting and aggregating

Indicators should be defined and an appropriate strategy for addressing double-counting determined. Next, standardized forms for recording whether a service has been provided should be developed and distributed to all service providers for standardized data collection and reporting across subnational areas. The most important forms are shown in Figure 21, and examples are included in Tools 7, 8 and 13.
Figure 17 shows a recommended data collection and reporting schedule for all levels.

Service providers routinely collect data on outputs, tally these numbers monthly, and share these data with the subnational level every quarter. At the national level, information should be aggregated from all service providers at each of the subnational levels. Specific tools are available that help with aggregating data at the subnational level. For example, the UNAIDS Country Response Information System allows service delivery providers to enter data directly online; software development is ongoing to provide automatic calculation of indicator values and graphs to look at data trends over time. If service providers do not have Internet access, the data should be aggregated by hand and entered on to spreadsheets or forms. Hard copies of these spreadsheets or forms should then be shared with the subnational or national level. Data should also be entered into the Country Response Information System or other computerized system at this stage.

**Figure 17: Recommended data-collection and reporting schedule for all levels**

![Figure 17: Recommended data-collection and reporting schedule for all levels]

---

**Data use**

*Assessing whether outputs meet targets*

One of the key questions in monitoring and evaluation is “What are we doing?” Part of the answer to this question is provided by an output monitoring system, which can accurately count people reached by interventions, service providers trained and commodities distributed. Subnational- and national-level programme managers can aggregate output data from the service delivery level to assess whether targets are being reached and then take actions to increase service outputs where needed.

Table 14 shows the number of needles and syringes distributed and the target number for the four service providers in a subnational area. Figure 23 shows the number distributed each month compared with the 3-month target.
Table 14
Needles and syringes: Number distributed, targets and percentage of target achieved

<table>
<thead>
<tr>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>January</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Distributed (1000s)</td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>February</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Distributed (1000s)</td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>March</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Distributed (1000s)</td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Looking at trends over time
Output trend analysis can improve services at the subnational level. A similar method should be used to monitor the outputs from different subnational areas at the national level. Trend analyses compare actual outputs with output targets over time.
Figure 19 presents data from four providers in the subnational area. The graph clearly indicates that Provider D is not reaching its targets.

**Figure 19: Example of a needle and syringe distribution – multiple service providers**

![Graph showing data distribution](image)

After receiving output data from service delivery providers, the subnational area level should provide timely feedback to the service delivery level. Underperformance should be discussed with the relevant stakeholders and perhaps with the target population. These discussions can reveal reasons for underperformance, show potential solutions and determine the steps to be taken.

### Additional resources

**Collecting, analysing and using monitoring data, entering data into the global spreadsheet, doing basic analysis and creating charts**


UNAIDS Country Response Information System


6.3 At the subnational level, how is coverage with a service or package of services calculated and interpreted (geographical coverage and population coverage)?

**Products**

**Coverage indicators**

Coverage indicators measure the proportion of subnational areas where a service is available or the proportion of the target population reached with each service or a package of services. Achieving adequate service coverage is an intermediate necessary step towards achieving behaviour change and reducing new HIV infections. Table 15 gives some examples of coverage indicators.

**Table 15**

**Definitions of coverage indicators**

<table>
<thead>
<tr>
<th>Type of coverage</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geographical coverage</td>
<td>Measures whether each service and package is available in each subnational area. Helps to identify areas where there should be services but there are currently none or few</td>
<td>Whether or not a needle–syringe programme is available in each subnational area</td>
</tr>
<tr>
<td>Population-level coverage</td>
<td>For a particular service Measures the proportion of people who inject drugs reached by the specified service (see Section 6.1 for a definition of “reached by a service”)</td>
<td>For a needle–syringe programme service, the percentage of people who inject drugs who have received needles and syringes from the programme</td>
</tr>
<tr>
<td></td>
<td>For a package of services Measures the proportion of the population reached with the specified package of services (see Section 6.1 for defining what is meant by “reached with package of services”)</td>
<td>For an HIV prevention package of services, the percentage of people who inject drugs who have received the package of services (received needles and syringes, information, education and communication materials and condoms)</td>
</tr>
</tbody>
</table>

**Methods**

**Calculate geographical coverage**

Table 16 shows an example of mapping the geographical distribution of services (see also Step 3) to calculate the geographical coverage of services.
## Table 16

**Example of geographical coverage calculation**

<table>
<thead>
<tr>
<th>Geographical availability of services</th>
<th>Area 1</th>
<th>Area 2</th>
<th>National</th>
<th>% of areas providing service (coverage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No service</td>
<td>Service available</td>
<td>No service</td>
<td>Service available</td>
<td>Number of areas providing service</td>
</tr>
<tr>
<td>Services for people who inject drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Needle–syringe programme</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Opioid substitution therapy or other drug-dependence treatment</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>HIV testing and counselling</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Antiretroviral treatment</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Targeted information, education and communication for people who inject drugs and their sexual partners</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Prevention and treatment of sexually transmitted infections</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Condom promotion programme for people who inject drugs and their sexual partners</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Vaccination, diagnosis and treatment of viral hepatitis</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Prevention, diagnosis and treatment of TB</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Structural and community interventions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addressing legal barriers</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Training and sensitization of service providers</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Community mobilization</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Establishment of safe spots</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Intervention package</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: numbers are intended to be illustrative and are not a recommendation.
Calculate population coverage

It is possible to estimate population coverage of services or the package of services by using service delivery data, or by conducting a representative survey of the target population that includes questions on the use of each service. Figure 20 illustrates the two strategies for estimating coverage.

Figure 20: Using Encounter forms or a population-based survey to calculate service coverage

Calculating the population coverage for a service or package of services using service delivery data requires:

- a clear definition of the service or package of services (see Step 3 and Section 6.1);
- a strategy to avoid double-counting clients (see Section 6.2);
- estimates of the size of the target population (see Section 1.4).
Figure 21 shows the calculation of coverage from service delivery data and a size estimate of the population.

For example, six service delivery providers in a subnational area each reached 200 people over the past year. Data from client encounter forms suggest that 50 of the 200 individuals at each service site also visited another service site in the same subnational area. The estimated size of the population in the subnational area is 3000. Coverage is \( \frac{(6 \times 150) + (6 \times 50/2)}{3000} = \frac{1050}{3000} = 34\% \).

See Step 2.1 for a description of how to conduct biobehavioural surveys of a representative sample from the target population. Surveys should include questions to assess coverage. Examples of questions to assess coverage are included in Tool 9.

**Comparing data sources**

Assessment of coverage by different methods and from different sources can produce different findings. Estimates of the extent of service provision, which are based upon programmatic data and estimates of target population size, are dependent upon various data sources. Furthermore, estimates of numbers of people who inject drugs carry a substantial amount of uncertainty. Programmatic data may also be incomplete or reported inaccurately. National data collection systems are often inconsistent or incomplete, and data may not be efficiently centralized or easily collated to produce national level data.

**Data use**

*How does coverage information help to improve performance?*

Coverage is a critical indicator of programme implementation. Programmes that are effective on a small scale will not achieve significant prevention objectives unless they are implemented at a scale that reaches the majority of the target population. Achieving high coverage is an intermediate step in promoting healthy injecting and sexual behaviours among people who inject drugs. The programme is
unlikely to result in behavioural changes if it does not reach its target audience. Coverage should be monitored to ensure that the specific coverage targets are being reached. To address coverage, the subnational and national levels need to ensure that all components of a package of recommended services are available and accessible. This implies responding to discriminatory laws, changing public attitudes, using advocacy to provide services to people who inject drugs, and addressing other sociodeterminants. When all components of the service package are available in the areas in need, efforts need to be made to provide better individual coverage. Timely feedback from the national level to the subnational level, and from the subnational level to service providers, may result in better coverage. Where underperformance is identified, it is necessary to examine data more carefully, analyse the reasons for the situation, identify potential solutions, determine the steps to be taken, and implement any changes needed to improve performance.

Figure 22 shows coverage indicators obtained from survey data, and Figure 23 shows coverage indicators for components of the package of services obtained from service delivery data. All indicators are included in Annex 2.

### Figure 22: Examples of coverage indicators (UNGASS indicator #9)

**Percentage of the Key Population reached with HIV Prevention Programmes, Sub-National Area A, Country X, 2010**

- Percentage of PWID who know where to get an HIV test
- Percentage of PWID who received condoms in the last 12 months
- Percent of PWID who received clean needles and/or syringes from NSP in the past 12 months
- Percentage of PWID reached with HIV Prevention Programmes

---

**Additional resources**

Operational guidelines for monitoring and evaluation of HIV programmes for people who inject drugs

Step 7: Outcome monitoring and evaluation. Are there changes in HIV transmission risk? Are these changes due to the HIV prevention programme?

Overview

Rationale: Why is this step important?

Targets were set in Step 3 for each outcome indicator based on baseline measures. Step 7 provides methods to assess whether, and by how much, these outcomes have changed and thus determine to what extent targets have been achieved. Two types of outcome are of interest: Outcomes related directly to risk of HIV transmission (i.e. biological determinants) and outcomes related to sociodeterminants (or underlying individual, community and structural factors) to risk and vulnerability for HIV infection.

Objectives: What will this step help you do?

- Determine whether there are any changes in the specified outcome indicators over time.
- Assess whether the outcome indicator targets were achieved.
- Determine the effectiveness of a specific programme in changing the specified outcome indicators.

Figure 23: Examples of coverage for components of the package of services

Table 17 lists the questions to be asked in order to determine whether Step 7 is appropriate or whether additional information is needed.

<table>
<thead>
<tr>
<th>Question</th>
<th>If Yes, go to Question</th>
<th>If No, go back to Step</th>
<th>If Yes, go to Question</th>
<th>If No, go back to Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 1: Have subnational areas been defined and mapped? Have the target population(s) and subgroups been defined?</td>
<td>2</td>
<td>1 – define areas and populations/subgroups</td>
<td>3</td>
<td>1–2 – define outcome indicators based on your epidemic</td>
</tr>
<tr>
<td>Question 2: Have outcome indicators at the national and subnational level been defined?</td>
<td>3</td>
<td>2 – define outcome indicators based on your epidemic</td>
<td>4</td>
<td>3 – set targets for each outcome indicator</td>
</tr>
<tr>
<td>Question 3: Have 3- to 5-year targets been set for each outcome indicator in each subnational area?</td>
<td>4</td>
<td>3 – set targets for each outcome indicator</td>
<td>5</td>
<td>4 – set targets for each outcome indicator</td>
</tr>
<tr>
<td>Question 4: Is the objective to monitor changes in outcomes or to evaluate whether the programme caused the changes(s)?</td>
<td>5</td>
<td>4 – set targets for each outcome indicator</td>
<td>6</td>
<td>5 – assess programme effectiveness</td>
</tr>
</tbody>
</table>

Figure 24 Step 7: Outcome monitoring and evaluation

Step 7. Outcome monitoring and evaluation: Are there changes in HIV transmission risk? Are these changes due to the HIV prevention programme?

Key questions

Methods

Products

Data use

7.1 Are there changes in the targeted outcomes?

Use mixed methods and appropriate analysis

Trends in outcome indicator data

Trend analysis can identify changes in the specified outcome indicators

7.2 Is the programme effective in changing specified outcomes?

Use mixed methods and data triangulation if appropriate

Changes in outcomes due to the programme

To identify strengths and weaknesses of a programme in order to improve it
There is a difference between outcome monitoring and outcome evaluation. **Outcome monitoring** tracks changes in outcomes without determining whether a specific programme caused any changes observed. **Outcome evaluation** determines whether changes in outcome indicators are caused directly by exposure to a prevention programme rather than (or over and above) other causes. Outcome evaluation requires a comparison group. Outcomes among the group or in the area exposed to a programme are compared with a group or area without the programme.

**How to answer key questions**

7.1 Are there changes in the targeted outcomes? Are there changes in the biological determinants of HIV transmission? Is there progress in the sociodeterminants of risk and vulnerability to HIV infection?

**Products**

**Trends in outcome indicators**

Trends in outcomes indicate whether changes have occurred or not. For specified outcomes related to biological determinants of HIV transmission (see Figure 32), outcome monitoring answers questions such as the following:

- Are there fewer or more people using non-sterile injecting equipment?
- Is condom use among people who inject drugs increasing or decreasing?

For outcomes related to sociodeterminants of HIV transmission, outcome monitoring answers questions such as the following:

- Have the laws changed to increase access to HIV prevention programmes?
- Do people who inject drugs know how to prevent HIV transmission?
Methods

Use mixed methods for outcome monitoring

The key to sound outcome monitoring and interpretation of the data is to use mixed methods (see Figure 27 and Box 7). Biobehavioural surveys are essential for measuring most of the outcomes related to biological determinants of HIV transmission (e.g. percentage of people using non-sterile injecting equipment at last injection) and for many of the sociodeterminants (e.g. stigma towards people living with HIV). Some sociodeterminants, however, such as the legality of needle exchange, are best assessed by other methods. Service delivery data can also be a rich source of information about people who have obtained services, and qualitative methods can provide important insights for interpreting the findings from surveys and client records.

Bio-behavioural surveys
- Can provide valid measures of indicators for each sub-group
- Can be repeated over time
- Can describe those at risk but not yet reached by services

Qualitative methods
- Can be conducted prior to bio-behavioural survey
- Can explore why people share needles
- Can identify contributing factors that increase risk
- Can identify barriers to accessing services and strategies for reducing barriers

Policy review
- Can track changes in policies and legal barriers

Service delivery data
- If a unique identifier code is used, can monitor trends in HIV transmission risk among individuals reached by the programme

Box 7

Example of the benefits of using mixed methods

A biobehavioural survey showed that the use of non-sterile injecting equipment is increasing. This finding sparked further analysis of the survey data: “What are the characteristics of those most likely to share needles? Have they visited a needle–syringe exchange programme in the past month?” In addition to survey data analysis, in-depth interviews and focus groups with the target population revealed that police were keeping youths away from needle–syringe programmes. The analysis also revealed that services were not available during after-school hours. These findings using qualitative methods led to meetings with the police and an assessment of the quality of services. Removing barriers to service access is anticipated to result in a reduction in use of non-sterile injecting equipment, which can be assessed during the next survey.

Repeated cross-sectional biobehavioural surveys

Repeated cross-sectional biobehavioural surveys provide an integrated and practical way for assessing coverage and outcome and impact (where appropriate) measures. Such surveys are the basis of “second-generation surveillance”. It is recommended that outcome indicators are collected once every 2 years. See Annex 2 for a list of outcome indicators related to biological determinants and sociodeterminants of HIV transmission.
Survey participants are asked about their use of specific services, about any facilitators or barriers to service use, and the quality of the services received. Information on the use of services (quantity, intensity) and on HIV-related risk behaviours should be obtained. This explores whether there is any evidence that people who use the services are less likely to have risky behaviours. Biobehavioural surveys can, but do not always, include HIV sero-status testing and can test for sexually transmitted infections. See Tool 9 for a list of illustrative survey questions and the corresponding indicators that can be obtained to assess coverage, outcomes and impact.

Box 8 gives an outline of a protocol for a behavioural survey study. A sound protocol is the basis for collecting good-quality data, good data management, and appropriate data analysis and use. Often the national programme will hire a consultant group to conduct the survey. The following criteria should be considered when selecting consultants for the survey:

- willingness to work with people who inject drugs;
- experience in sampling hidden populations;
- experience in designing surveys that are valid and understandable by the survey population;
- experience with obtaining ethical review approval;
- experience in collecting data for the relevant outcome indicators;
- experience in data entry and documentation;
- experience in identifying, hiring, training and supervising interviewers;
- willingness to share data and explore initial findings with key stakeholders;
- likelihood that the protocol can be implemented again in future years;
- justified costs and proven track record for timely delivery.

Box 8

**Protocol outline for outcome monitoring**

**Background:**
- prevalence of HIV infection among people inject drugs over time from surveillance data;
- involvement of stakeholders in planning the study.

**Study population:**
- map of subnational area(s), including contextual barriers and facilitators for risk;
- estimates of the size of the population of people who inject drugs in the area;
- operational definition of people who inject drugs and eligibility criteria;
- description of subgroups to be monitored.

**Outcomes to be monitored:**
- list of outcomes related to HIV transmission risk and sociodeterminants to be measured;
- targets for each outcome for subnational area(s) and national level.

**Exposure to HIV prevention services (required for outcome evaluation):**
- description of the package of services;
- operational definition of coverage for each service;
- rationale for survey questions selected to assess exposure to each service;
coverage indicators defined.

**Brief description of the study design:**
- e.g. repeated cross-sectional survey of people who inject drugs;
- frequency of repeating the survey, e.g. every 3 years;
- description of any efforts to use the data to estimate the size of the population.

**Sample size needed to track changes in outcome indicators:**
- sample size calculations should be conducted before implementation and if possible should include equal proportions of males and females and people aged 15–24 years and 25–49 years.

**Sampling strategy:**
- rationale for sampling strategy selected.

**Interviewing mode and incentive payments:**
- face-to-face or self-completed or computer-assisted survey;
- cash or in-kind compensation.

**Methods for cost–effectiveness analysis (useful for outcome evaluation).**

**Data-collection forms:**
- forms for sampling frame;
- informed consent forms;
- questionnaire.

**Training materials:**
- sampling frame development;
- interviewer and supervisor training;
- training in ethics and confidentiality.

**Pilot study:**
- target number of individuals for data collection;
- changes based on pilot study findings.

**Data entry and data storage.**

**Data analysis:**
- sociodemographic characteristics – trends over time;
- outcomes related to HIV transmission risk – trends over time;
- outcomes related to sociodeterminants – trends over time;
- for each subnational area and for national level.

Data interpretation, data dissemination and use.
Adherence to protection of human subjects and procedures to ensure privacy and confidentiality of data.

Budget and time schedule.
Choosing a sampling method is one of the key decisions in conducting a biobehavioural survey. Table 18 lists some of the sampling methods available, and their benefits and drawbacks.

Table 18
Sampling methods

<table>
<thead>
<tr>
<th>Type of sampling</th>
<th>Key features, including recruitment</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respondent-driven sampling</td>
<td>Initial seeds recruit additional respondents, who recruit 2–4 additional respondents and get an incentive payment for their own interview and the interview of their contacts</td>
<td>Recruitment uses coupons to keep track of recruitment chains and allow calculation of selection probabilities, qualifying the method as a probability method</td>
<td>If people do not randomly recruit from their network, the sample may be biased</td>
</tr>
<tr>
<td>Time location sampling (venue-based)</td>
<td>Venues where people who inject drugs can be reached are identified and organized into a sampling frame with hours of operation identified; either a random sample of hours or a sample of busy times is selected</td>
<td>Selection probabilities can be calculated so this qualifies as a probability method; the method is replicable and verifiable</td>
<td>People at venues may not want to be interviewed; some people may not visit venues; venues change over time</td>
</tr>
<tr>
<td>Targeted/quota sampling</td>
<td>Ethnographic assessment identifies subgroups; quotas recruited by convenience from each group</td>
<td>Obtains a diverse sample</td>
<td>Final sample is not a probability sample</td>
</tr>
<tr>
<td>Facility sampling</td>
<td>People visiting the facility are selected for interview (e.g. the first 200 patients in a month)</td>
<td>Convenient, reaches people who use facilities</td>
<td>People using services are not representative of entire population</td>
</tr>
<tr>
<td>Snowball sampling/chain referral</td>
<td>Initial recruits (“seeds”) recruit participants, who recruit additional participants, until sample target is reached</td>
<td>Historically useful in obtaining access to hidden populations</td>
<td>Chain may not reach a representative sample of population</td>
</tr>
<tr>
<td>Internet survey</td>
<td>People are recruited from Web sites of interest to people who inject drugs</td>
<td>Participation is voluntary; survey is inexpensive relative to surveys that require interviewers</td>
<td>Sample is a convenience sample and is biased; no HIV testing (i.e. no HIV prevalence estimate can be obtained)</td>
</tr>
</tbody>
</table>

Source: Adapted from several sources, including Surveillance among most at risk populations for HIV. Geneva, Joint United Nations Programme on HIV/AIDS and World Health Organization, 2011; and Wilson, D. A monitoring and evaluation framework for concentrated epidemics and vulnerable populations. Washington, DC, Global HIV/AIDS Monitoring Team.
Calculate national outcome indicators

The most important trends to monitor are those within each subnational area. It is often useful, however, to have a national estimate that takes into account the indicator values from all of the subnational areas. Table 19 presents a method to calculate national estimates. In this example, the indicator ranges from 20% to 80% locally. The national estimate is 50%.

Table 19
Calculating a national estimate from outcome measurements in subnational areas

<table>
<thead>
<tr>
<th>Area</th>
<th>Size of population of people who inject drugs</th>
<th>Indicator (e.g. % using a condom at last sex)</th>
<th>Number of individuals meeting indicator requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subnational area 1</td>
<td>15 000</td>
<td>40%</td>
<td>6000</td>
</tr>
<tr>
<td>Subnational area 2</td>
<td>5000</td>
<td>20%</td>
<td>1000</td>
</tr>
<tr>
<td>Subnational area 3</td>
<td>30 000</td>
<td>50%</td>
<td>15 000</td>
</tr>
<tr>
<td>All other subnational areas</td>
<td>10 000</td>
<td>80%</td>
<td>8000</td>
</tr>
<tr>
<td>National estimate</td>
<td>60 000</td>
<td>30 000/60 000 = 50%</td>
<td>30 000</td>
</tr>
</tbody>
</table>

Note: numbers are intended to be illustrative and are not a recommendation.

Data use

Using graphs to present trends in outcome indicators

Figure 32 illustrates outcome monitoring for three indicators related to transmission risk in a subnational area. The figure presents interview responses from men sampled using respondent-driven sampling.

Box 9 includes some tips on making a graph both informative and easy to read.

Box 9

What makes a graph easy to read and informative?

- The graph can stand alone, without additional text.
- Titles and legends are well written.
- Information is given about the sample size and how the sample was recruited.
- Information is given about the geographical area where the data were collected.

Actions based on trends in outcome data

Figure 28 shows the further investigations that should be undertaken based on the results from outcome monitoring.
Additional resources: Choosing a sampling method


7.2 Is the programme effective in changing specified outcomes?

An outcome evaluation assesses whether any changes in outcomes were caused by a specific programme rather than other factors. It is helpful to know that people who inject drugs have increased the use of sterile injecting equipment (i.e. data from outcome monitoring), but did they do so because of the programme (i.e. data from outcome evaluation)? Deciding whether an evaluation is needed requires a clear understanding of what it is already known about the programme. Many of the basic questions about efficacy\(^1\) and effectiveness\(^2\) have already been resolved for HIV prevention interventions for people who inject drugs. If there are no major external factors that are expected to affect scale-up, then it may suffice to monitor whether the programme is being implemented according to plan (see Steps 4–6) and achieving its intended effects (see Section 7.1). If there are important uncertainties about the programme, however, then an evaluation is warranted.

The main objective of an evaluation is to inform decision-making about the programme. The complexity and precision of the evaluation (i.e. adequacy, plausibility or probability) depends on who the decision-maker is and what types of decision will be taken because of the findings (see Table 20).

---

\(^1\) An efficacy study assesses whether the programme works under carefully controlled conditions (i.e. in expert hands, fully resourced and with clearly defined conditions).

\(^2\) An effectiveness study assesses whether the programme works in the real world (i.e. implemented as part of routine practice or in a community setting with limited resources and capacity). Source: Habicht JP et al. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. International Journal of Epidemiology, 1999, 28:10–18.
These considerations, together with time and resource limitations, determine which evaluation methods should be used. The strengths and weaknesses of different evaluation approaches should be compared carefully.

Table 20

Characteristics of evaluations

<table>
<thead>
<tr>
<th>Type of evidence</th>
<th>Type of statement</th>
<th>Comparison group/criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequacy</td>
<td>Expected change occurred (but no causality)</td>
<td>No control or comparison group; predefined criteria (absolute or incremental value)</td>
</tr>
<tr>
<td>Plausibility</td>
<td>Programme seemed to have an effect over and above external influences based on ruling out step by step other potential alternative explanations for observed changes</td>
<td>Non-random control or comparison group or area (historical, external, internal or simulated)</td>
</tr>
<tr>
<td>Probability</td>
<td>Programme has an effect with only a very small probability that the difference between intervention and control comparison groups or areas was due to confounding, bias or chance</td>
<td>Control or comparison group or area selected by randomization</td>
</tr>
</tbody>
</table>

An outcome evaluation requires additional effort and resources. Any outcome evaluation should be preceded by formative research and a well-defined programme impact pathway based on the best available evidence and programme experience to date. All outcome evaluations should include an extensive process evaluation to fully understand the implementation of the programme and to allow for timely corrective action where needed.

Figure 29: Outcome evaluation data of a needle–syringe programme

Note: Effect of the needle–syringe programme on self-reported use of clean needles at last injection: In crude analysis, use of sterile injecting equipment above 20% can be attributed to the intervention because 20% use of sterile injecting equipment was achieved in the absence of an intervention (given that all other conditions were identical or similar).
Products

Outcome data linked to a specific programme

Figure 36 shows the difference in outcomes related to risk for HIV transmission in areas exposed to a certain programme compared with outcomes in areas that were not exposed to the programme. In the intervention area, the outcome indicator increased positively over time. The difference (20% vs 80%) can be attributed to the programme if the protocol for collecting and analysing the data was sound and well implemented.

Methods

An outcome evaluation protocol is similar to an outcome monitoring protocol (see Section 7.1) but includes the following additional information:

- Information to assess programme coverage among people who were supposed to receive the programme: This includes a clear description of the programme and how it was implemented, the target population, the intensity of programme coverage (e.g. reached six times by a needle–syringe programme), and the completeness of programme exposure (e.g. reached by five components of the recommended package). It can be analysed in terms of changes in outcome indicators.

- Information to assess the size of the population of people who inject drugs in the target area to facilitate assessment of coverage: Within the survey, questions can be asked about whether the person has been in prison or in hospital or is receiving opioid substitution therapy. The proportion of people reporting these contacts with facilities during a specified period can be used to estimate the number of people who inject drugs if there is known information on the unique number of people who have contact with the facilities during the specified period. Information on the cost of providing services can allow cost-effectiveness to be estimated.

- Information on people or groups in the target area who did not receive the programme or information about similar people in a comparison area that did not receive the intervention.

Conduct an outcome evaluation using mixed methods and data triangulation analysis

Typically, programme managers at the national level are interested in evaluating the effects of the overall HIV prevention programme. They are interested in evaluating the programme’s different components (e.g. programmes targeting people who inject drugs) related to HIV-related risk behaviours and HIV incidence (see Step 8).

The following methods are recommended for HIV prevention including, but not restricted to, programmes for people who inject drugs:

- Establish criteria for determining effectiveness with high plausibility that the observed trends are due to the programme and not other factors. For example, the Bradford Hill list of considerations about causality may be used as a guide to establishing a clear picture about the effects of the programme that are convincingly plausible (see Box 10).

- Document the implementation of the HIV prevention programme and its performance using data from routine programme monitoring, process evaluations and performance assessments.

- Prospectively collect data that describe the programme in detail, including the content of the intervention package, the intervention coverage (i.e. who and where), the quality and the duration.

- Establish a range of data sources for outcome data, including regular surveys. Conduct special studies to address any data gaps (e.g. in-depth social and behavioural studies of determinants of HIV vulnerability and risk, experimental or quasi-experimental studies, and cost-effectiveness analyses of the different programme components). Draw on the expertise of programme beneficiaries and front-line service providers to validate the evaluation findings.
Analyse all available data to determine whether the observed changes can reasonably be attributed to the programme (such as the Bradford Hill considerations). This process is known as “data triangulation”. It should be conducted in a participatory manner to include decision-makers, evaluators, programme managers, service providers and programme beneficiaries. Mathematical modelling can be used to simulate control groups or control areas in the data analysis. Combining data from different data sources (i.e. convergence of evidence) provides sufficient evidence for a causal link.

Box 10

Bradford Hill considerations for determining plausible association

- **Strength of association**: The stronger the association, the less likely it is simply reflecting the influence of some other factor(s). This includes consideration of statistical precision and methodological rigour of the existing studies with respect to bias (selection, information, confounding).
- **Consistency**: Replication of findings by different investigators, at different times, in different places, with different methods, and the ability to convincingly explain different results.
- **Specificity of the association**: There is an inherent relationship between specificity and strength – the more accurately defined the disease and exposure, the stronger the observed relationship should be.
- **Temporality**: The ability to establish that a cause preceded the presumed effect.
- **Biological gradient**: Incremental change in disease rates in conjunction with corresponding changes in exposure; verification of a dose–response relationship consistent with the hypothesized conceptual model.
- **Plausibility**: People are more willing to accept the case for a relationship that is consistent with their general knowledge and beliefs.
- **Coherence**: How well do all the observations fit with the hypothesized model to form a coherent picture?
- **Experimental evidence**: The demonstration that, under controlled conditions, changing the exposure causes a change in the outcome.
- **Analogy**: People are more willing to accept arguments that resemble other arguments that they already accept.

These considerations are a guide only and should not be used as criteria for scoring or weighting.


**Use experimental and quasi-experimental designs**

Consider using an experimental or quasi-experimental design to evaluate a new programme that has not been evaluated previously. This should be done when the effectiveness of the programme is unknown, the programme is politically or otherwise risky, or there is potential for negative effects.

Figure 37 shows a flowchart for a randomized community trial, and Table 21 lists some of the features and considerations of this sort of trial.
An experimental design generally requires high capacity and resources in order for the experiment to be implemented and the findings analysed well. Randomization should be considered carefully in terms of size and timing of effects, likelihood of selection bias, feasibility and acceptability of experimentation, and cost (Craig et al., 2008). Experience with a range of alternative adaptive designs and with sophisticated analysis techniques is growing. Appropriate expertise should be sought to decide whether an experimental design is needed and, if so, to design, conduct and analyse the study.

Due to complexity in design, implementation, analysis and interpretation, a community randomized trial should be considered only if there is a well-defined narrow hypothesis to identify success or failure of the key intervention, and there is a measurable intervention in order to assess its implementation, and there are well-defined measurable outcomes. These conditions also apply to the use of quasi-experimental designs (see below).
Figure 31 shows a flowchart for a non-randomized community trial, a type of quasi-experimental design, and Table 22 lists some of the features and considerations of this sort of trial.

### Figure 31: Flowchart for a non-randomized community trial

![Flowchart for a non-randomized community trial]

### Table 22

**Characteristics of a non-randomized community trial**

<table>
<thead>
<tr>
<th>Features</th>
<th>Requirements and considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some areas are selected using a method other than randomization to receive the intervention. Baseline and follow-up surveys are conducted in each area</td>
<td>Randomization may not be politically feasible or ethically responsible. The design is feasible if there are several priority areas for intervention in a country and a willingness to collaborate</td>
</tr>
<tr>
<td>Interpretation: The difference between randomized and comparison areas is probably due to the intervention, although there may be other explanations</td>
<td>One cannot readily assume that any observed differences in measurements between the areas are due only to the programme. Information on the similarity of intervention and comparison areas is needed to interpret the results</td>
</tr>
</tbody>
</table>

Figure 32 shows a flowchart for a pre–post trial, and Table 23 lists some of the features and considerations of this sort of trial.

### Figure 32: Pre–post trial

![Flowchart for a pre–post trial]
Table 23
Characteristics of a pre–post trial

<table>
<thead>
<tr>
<th>Features</th>
<th>Requirements and considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within a selected area, baseline and follow-up measurements are conducted</td>
<td>Interpretation of pre–post outcome evaluations is difficult. The first set of pre–post comparisons should be interpreted with extreme caution. Results from pre–post measurements become more compelling if there is complementary information from service delivery statistics and if the findings are repeated in subsequent measurement rounds</td>
</tr>
<tr>
<td>Interpretation: The difference in outcomes before and after the intervention may be due to the intervention if there is evidence that there are no competing explanations</td>
<td></td>
</tr>
</tbody>
</table>

Because of the lack of a comparative element in this type of evaluation, it is difficult to conclude whether any observed changes were due to the programme or other factors. For this reason, the methods described under evaluation design using mixed methods and data triangulation analysis in Section 7.2 should be used to build a plausible case of association between the programme and the observed results. Good evidence supporting the package of recommended services is already available for HIV prevention among people who inject drugs. Therefore, there is little need to conduct experimental or quasi-experimental evaluations in this population.

**Data use**

*Using summary tables and graphs*

Templates for tables and graphs are developed during the planning stage of the evaluation. The following measures should be included in the full evaluation report for the entire population and for key subgroups at baseline and at follow-up in intervention and control or comparison groups or areas:

- sociodemographic characteristics;
- outcome indicators related to transmission risk (e.g. injecting drug use, sexual behaviour);
- indicators related to sociodeterminants (e.g. stigma, incarceration);
- prevalence of HIV and sexually transmitted infections (if relevant);
- exposure to each prevention service and to the full package;
- association between exposure to the full package and risk behaviour.

Table 24 is an example summary table to compare indicators among the entire population and among subgroups in intervention and comparison areas. See Annex 2 for a list of outcome indicators. In addition to summary tables, key indicator results should be presented in a graph. The Goals Model modelling software can be used to estimate a programme’s effect on behaviour change. Observed behaviours can be plotted against estimated levels of behaviour had no intervention taken place. In this way, the Goals Model helps in understanding the extent to which the observed changes in behaviours are attributable to the programme (see Section 8.2).
### Table 24

**Summary table for comparing indicator data**

Table: Include title indicating populations, method, period of data collection and geographical areas

<table>
<thead>
<tr>
<th>Population</th>
<th>Baseline (year)</th>
<th>Follow-up 1 (year) (add more columns with subsequent measurements)</th>
<th>Measure of effect (odds ratio*)</th>
<th>Indicator target</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Comparison area</td>
<td>Intervention area</td>
<td>Comparison area</td>
<td>Intervention area</td>
</tr>
<tr>
<td>All surveyed</td>
<td>Number surveyed</td>
<td>Number surveyed</td>
<td>Number surveyed</td>
<td>Number surveyed</td>
</tr>
<tr>
<td>Indicator 1</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
</tr>
<tr>
<td>Indicator 2</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
</tr>
<tr>
<td>Subgroup 1 (e.g. women aged 15–24 years)</td>
<td>Number of women aged 15–24 years surveyed</td>
<td>Number surveyed</td>
<td>Number surveyed</td>
<td>Number surveyed</td>
</tr>
<tr>
<td>Indicator 1</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
</tr>
<tr>
<td>Indicator 2</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
<td>Estimate with confidence interval</td>
</tr>
</tbody>
</table>

*The odds ratio gives an indication of how much higher or lower the indicator is in the intervention compared with the comparison area. For example, if the indicator is 30% in the intervention area and 10% in the comparison area, then the crude odds ratio is 3. Computer programmes can estimate how precise the estimate is based on the actual data and provide a confidence interval around the estimate.

**Good data management is essential for data use**

Monitoring and evaluation are ongoing activities. Measurement surveys will be repeated and data compared across years and across areas. This has implications for study protocols, data collection methods and data management. Protocols and methods should not change substantially from year to year, so that indicator data remain comparable over time.

If problems with a protocol are uncovered that question previous findings, it may be time to reassess the protocol. Any substantial changes should be made cautiously and based on objective assessments of the protocol under question. If the protocol has to be changed, the anticipated strengths of the new protocol should be documented relative to the previous protocol and these assumptions tested to the extent possible. Standard templates that allow data to be added with each subsequent measurement are useful and can save time.

Data from each measurement period should be maintained in a specific dataset. The M&E representative in each area should have access to the data from their area. In addition, a national dataset that
includes all comparable data across areas and over time should be prepared and documented. The national dataset facilitates comparative analyses.

When merging datasets from different areas and different years, attention should be paid to the following:

- For each record in the dataset, include information about the date of the study, the area, whether the survey took place when the area was a designated intervention or comparison area, the sex of the respondents, and each subgroup of the respondents.
- Use consistent variable names across all measurement periods.
- Document in a table the comparable survey question numbers (e.g. the variable “Sex” is Question 2 in 1998 and Question 5 in 2000).

**Feedback workshops: A key component of a good data dissemination strategy**

Local feedback from programme managers and key populations should be included in the dissemination strategy. Key people from several areas may want to meet and compare findings informally before a national meeting is organized (see also Step 8 for dissemination strategies).

A well-conducted outcome evaluation includes a local assessment of the face validity of the findings. If the evaluation shows a decrease or increase in risky behaviour, the following questions must be asked before concluding that the change was due to the intervention:

- Is it reasonable to believe that the programme caused the changes in outcome?
- Is information available on how the programme was implemented and the context in which it was implemented?
- What services were included in the programme delivery?
- Were the services sufficiently funded?
- Were the services implemented according to plan?
- Did the services actually occur?
- Did the observed outputs reach the targets set for the service(s)?

One way to investigate the findings of an outcome evaluation is to set up a mock debate in which the same service delivery data, survey data and outcome evaluation findings are used by two teams. One team can argue that the intervention was not effective and the other team can argue that the intervention was effective.

**Additional resources**

**Evaluation methods**


Step 8: Impact monitoring and evaluation. Are the combined HIV prevention activities in the country changing the HIV epidemic among people who inject drugs?

Overview

Rationale: Why is this step important?
The ultimate goal of any HIV prevention programme for people who inject drugs is to reduce the number of new HIV infections. Reducing the number of infections among people who inject drugs is part of a broader strategy to reduce the number of new HIV infections within the general population.

Objectives: What will this step help you do?
- Determine the level and trends of HIV prevalence (overall, by subnational area and by subgroup).
- Determine, where possible, trends in HIV incidence (overall, by subnational area and by subgroup).
- Determine, where possible, trends in HIV-associated mortality (overall, by subnational area and by subgroup).
- Determine whether these trends relate to a change in risk behaviours or are a reflection of the natural history of the HIV epidemic among people who inject drugs.
- Determine what factors (programmatic and contextual) may be associated with the observed trends.

Impact monitoring describes trends in HIV prevalence, HIV incidence or HIV-related mortality. Impact evaluation assesses whether changes in HIV prevalence or incidence can be attributed to the overall HIV prevention programme for people who inject drugs.

Use the data collection methods used in Steps 1 and 2 again. At this stage, we are not concerned about attributing the observed changes to any one specific project or set of services; instead we are interested in the collective effectiveness of the overall HIV prevention programme in the country or subnational area.

As explained in Step 1, HIV prevalence can be used as a proxy measure for HIV incidence (see Box 11). Interpreting national HIV prevalence and incidence trends is a challenge. It is necessary to be able to distinguish between the expected saturation and decline of HIV prevalence without behaviour change and declines associated with reduced risk while accounting for improved survival on antiretroviral treatment.
Box 11

Difference between HIV incidence and HIV prevalence

The annual HIV incidence is defined as the rate of new HIV infections occurring during a year for every 100 (or 1000) people at risk of infection at the start of the year. HIV prevalence is the proportion of the population infected with HIV at any point in time. For example, in a population of 120 people who inject drugs, if 20 people are currently living with HIV, the HIV prevalence is 18%. Of the remaining 100 people, if 10 become infected with HIV in the next year, the HIV incidence would be 10% (i.e. 10/100) and the HIV prevalence would rise to 25% (30/120) if there are no deaths in the population.

How to answer key questions

8.1 How should trends in HIV prevalence be monitored?

Products

Trends in HIV prevalence or HIV incidence

Figure 34 shows trends in HIV prevalence among people who inject drugs in Bangkok, Thailand, in sentinel sites.

Methods

Conduct impact monitoring

Impact monitoring does not determine whether changes in HIV incidence or prevalence are a result of a programme. Impact monitoring is similar to outcome monitoring (see Section 7.1); the difference is that instead of tracking condom use or injecting drug behaviour, the focus is on prevalent or incident HIV infection.
The most efficient way to monitor impact is to collect or use existing data on HIV prevalence by age and data on the time since initiating risky behaviours such as injecting drugs or having unprotected intercourse. These data allow for assumptions that young people and specifically “new initiators” are recently infected. For example, if a 23-year-old man who injects drugs and is living with HIV reports that he first had intercourse and began injecting 2 years ago (aged 21 years), then it is reasonable to assume that he has been infected in the previous 2 years. Therefore, he is considered as having been recently infected (or as an incident case).

Interpretation of HIV prevalence trends is not straightforward. A decrease in the prevalence of HIV infection does not necessarily indicate that there are fewer new infections. For example, if the number of new HIV infections is increasing, HIV prevalence can decrease if people living with HIV die. Trends in HIV infection among recent initiators are less likely to decrease based on mortality, which makes age-specific prevalence of recent initiators a useful proxy for recently acquired infections. See Additional resources for UNAIDS and WHO guidelines that give a full description of methods to estimate HIV prevalence and incidence.

If behavioural surveys do not currently include HIV testing, then such inclusion should be considered for reasons that extend beyond measuring impact. Adding HIV testing to a behavioural survey is extremely useful for identifying the characteristics of people who are living with HIV and tracking the epidemic in the population. The need for additional time, effort and cost, however, should be carefully considered and addressed, with attention paid to the following issues:

- cost of HIV testing, training, supplies, record-keeping, and possible incentive payments;
- issues regarding informed consent, need for counselling, provision of test results and confidentiality of test results;
- how to encourage people living with HIV who already know their status to participate in the survey;
- whether testing may increase stigma associated with participating in the survey;
- possible need to increase sample size if a precise estimate of HIV prevalence is needed.

HIV-associated mortality is a key impact indicator. Few settings have the resources or systems to measure mortality associated with HIV among people who inject drugs, however. If mortality data are available, they may be used by linking to cohort data or compared with increases in antiretroviral treatment.
Operational guidelines for monitoring and evaluation of HIV programmes for people who inject drugs

(Pacheco et al., 2009). HIV case surveillance with a follow-up component can effectively capture HIV-related mortality and probable mode of HIV transmission, as well as treatment history (Zhang et al., 2009). Mortality data specific to people who inject drugs are difficult to obtain. Improvement of civil registration and HIV case-reporting systems will ultimately lead to such data becoming available, but a full discussion of this is beyond the scope of this document (see WHO and UNAIDS recommendations for the improvement of mortality data collection, which will be released in 2011).

8.2 Are HIV prevention programmes reducing new infections?

**Products**

*Impact data linked to the HIV prevention response (UNAIDS, 2010 Global Report)*

Figure 35 shows the link between harm-reduction programmes and HIV prevalence in Ukraine.

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**Figure 35: Harm-reduction programmes and HIV prevalence in Ukraine**


*Sources: Country Progress Reports 2010. M Mary, C Chna, G T Sfis, G O Vemres, R Lveris (2010). A proxy measure for HIV incidence among populations at increased risk to HIV. Vol 2(1).* *Journal of HIV/AIDS Surveillance and Epidemiology*

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**Methods**

*Conduct an impact evaluation using data triangulation analysis and modelling*

Conducting a comparative evaluation study to establish the effect of a specific programme on HIV infection is particularly challenging and not cost-effective. Measuring incident HIV infection would require the participation of thousands of people in the study in order to expect a detectable difference in new infections between the intervention and the comparison areas that may be due to the intervention. For example, in a recent study of a possible HIV vaccine in Thailand, the difference in the number of new HIV infections in the intervention group compared with the control group was fewer than 20, although the number of people enrolled in the study was over 4000.
A better approach is an integrated analysis (i.e. data triangulation analysis) of trends in a range of comparable and consistent national or subnational data on behavioural and other outcomes and on HIV data; this may also include other sexually transmitted infections data and other impact data, as appropriate. See Additional resources for detailed guidelines on data triangulation analysis.

Modelling can play an important role but needs to be applied in an appropriate manner. Modelling relies heavily on the availability of good-quality data to yield meaningful results. A range of approaches should be combined to analyse trends in HIV incidence, since there is no single perfect modelling technique. These data triangulation and associated modelling analyses need to be conducted by experienced data analysts and with involvement of a wide range of stakeholders (see Section 7.2).

Examples of modelling techniques: Modes of Transmission (MoT) and the GOALS Model

Spreadsheet tools are available to explore the possible effect of HIV prevention programmes on the HIV epidemic. For example, the MoT spreadsheet uses a set of assumptions about HIV infectiousness and transmission probabilities to estimate the number of new HIV infections among people who inject drugs as well as the overall HIV incidence among people who inject drugs. The inputs necessary to use this model are given in Table 25. These inputs can be obtained from biobehavioural surveys and good estimates of the size of the population.

Table 25
Data required for a Modes of Transmission (MoT) analysis for people who inject drugs

<table>
<thead>
<tr>
<th>Data required</th>
<th>Corresponding indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of population</td>
<td>Number of people who inject drugs</td>
</tr>
<tr>
<td>HIV prevalence</td>
<td>Prevalence of HIV among people who inject drugs</td>
</tr>
<tr>
<td>Prevalence of sexually transmitted infections</td>
<td>Prevalence of sexually transmitted infections among people who inject drugs</td>
</tr>
<tr>
<td>Percentage of injecting acts that are protected</td>
<td>Percentage of all injecting drug acts in the past 7 days that were with sterile injecting equipment; or percentage of people who inject drugs reporting the use of sterile injecting equipment the last time they injected</td>
</tr>
<tr>
<td>Number of injecting partners per year</td>
<td>Mean number of injecting partners in the past 30 days</td>
</tr>
<tr>
<td>Number of needle-sharing acts per partner</td>
<td>Mean number of acts of needle-sharing with each injecting partner in the past 30 days</td>
</tr>
<tr>
<td>Transmission probability per injecting drug act</td>
<td>Probability of transmitting HIV during each injecting drug act (use literature values already input in model)</td>
</tr>
</tbody>
</table>
The Goals model and the Asian Epidemic Model are other examples of computer modelling software within the Estimation and Projection Package (Spectrum) that can help in the planning and evaluation of programmes. Such software is quite technical and will likely require expert consultation. For example, the Goals Model can predict answers to the following questions:

- What would be the national prevalence among people who inject drugs if we had not implemented our activities? Would the same changes have occurred if we had done nothing at all?
- How many new HIV infections among people who inject drugs did we avert due to the increased coverage of our activities?
- What was the cost for each estimated new HIV infection averted among people who inject drugs? Are our activities cost-effective?

It is clear from these examples that modelling requires a range of data that may not be available in some countries.

**Data use**

*Preparing a national evaluation report*

The most common way to share the information of an evaluation is through a report that includes detailed statistical analysis of data collected throughout the M&E cycle. This report will serve as a foundation for all other data-dissemination products targeting different audiences. Important findings in the evaluation report, and their implications for policy formulation, programme planning and improvement, and resource allocation, should be clearly highlighted in the report. The recommendations should be written in a manner that is readily accessible to a range of audiences.

The following should be included in a national evaluation report on the impact of HIV prevention on the HIV epidemic among people who inject drugs:

- executive summary (including findings and recommendations for policy formulation, programme planning and improvement, and resource allocation);
- background information;
- objectives of the evaluation;
- evaluation methods used;
- detailed data analysis and evaluation findings;
- discussion and interpretation of the evaluation findings;
- recommendations for policy formulation, programme planning, and improvement and resource allocation;
- recommendations for additional data collection to address key information gaps.

*Dissemination of evaluation findings*

One of the most important aspects of evaluation is disseminating the results to key partners. This provides feedback to the national HIV prevention programme on prevention activities from the community. Sharing the results also informs policy-makers, donors and evaluators about the current status of the HIV epidemic among people who inject drugs. This has the potential to influence policy, funding and future programmes and to broaden societal awareness of the HIV epidemic among people who inject drugs.
Recipients of a national evaluation report include:

- people who inject drugs;
- policy-makers and decision-makers (e.g. Ministry of Health, Office of the President);
- programme managers and people responsible for M&E at all levels;
- programme funders and international donor organizations (e.g. Global Fund, World Bank);
- the research community (e.g. national and international universities);
- community members and organizations (e.g. NGOs, community leaders);
- the general public;
- the mass media.

The dissemination products should be tailored to the specific audiences. Some examples are listed in Table 26.

Table 26
Tailored products and methods for disseminating evaluation findings

<table>
<thead>
<tr>
<th>Dissemination methods</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briefing materials</td>
<td>Aimed at press and mass media</td>
</tr>
<tr>
<td></td>
<td>Avoid technical language</td>
</tr>
<tr>
<td></td>
<td>Focus on one or two key findings</td>
</tr>
<tr>
<td>Policy briefs</td>
<td>Aimed at leaders and policy-makers</td>
</tr>
<tr>
<td></td>
<td>Focused on one or two key findings</td>
</tr>
<tr>
<td></td>
<td>Discuss implications of findings</td>
</tr>
<tr>
<td></td>
<td>Give recommendations towards future prevention activities</td>
</tr>
<tr>
<td></td>
<td>Develop tailored briefs for different policy-makers</td>
</tr>
<tr>
<td>Group meetings and presentations</td>
<td>Aimed at people who inject drugs, groups of policy-makers, programme managers or the general public</td>
</tr>
<tr>
<td></td>
<td>Present key findings</td>
</tr>
<tr>
<td></td>
<td>Answer questions</td>
</tr>
<tr>
<td></td>
<td>Discuss implications for programme improvement</td>
</tr>
<tr>
<td>Individualized meetings and presentations</td>
<td>Aimed at influential people (policy-makers, community leaders, NGOs, national/subnational programme managers)</td>
</tr>
<tr>
<td></td>
<td>Highly personalized</td>
</tr>
<tr>
<td></td>
<td>Share key results and discuss implications for programme improvement</td>
</tr>
<tr>
<td></td>
<td>Needs time and intensive preparation to be used effectively</td>
</tr>
</tbody>
</table>

Additional resources

Data triangulation and evaluating impact of HIV prevention

Data triangulation for HIV prevention program evaluation in low and concentrated epidemics. Bangkok, FHI Asia Pacific Regional Office, 2010.


Dissemination of evaluation findings

Notes
Notes