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EUROPEAN UNION DRUGS AGENCY

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Drug-related infectious diseases (DRID) technical protocol – surveys on HIV and viral hepatitis in people who inject drugs

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Legal notice

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Abbreviations

ART	antiretroviral therapy
DRID	drug-related infectious diseases
EASL	European Association for the Study of the Liver
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU	European Union
EUDA	European Union Drugs Agency
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
NSP	needle and syringe programme
OAT	opioid agonist treatment
PLHIV	people living with HIV
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RDS	respondent-driven sampling
STI	sexually transmitted infections
SVR	sustained virologic response
UN	United Nations
VL	viral load
WHO	World Health Organization

Introduction

Background

Drug use increases the risk of HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) infections, and drug-related infectious diseases (DRID) contribute to a high morbidity and mortality among people who inject drugs (PWID) (Degenhardt et al., 2016; 2017; 2023). Moreover, in many countries, inadequate coverage of harm reduction services and existing structural barriers continue to limit access to healthcare for PWID which contributes to this key population being disproportionately affected by HIV and viral hepatitis (EMCDDA, 2021; WHO, 2022).

The European Union Drugs Agency (EUDA) ([1]) monitors drug-related harms, including DRID and preventive measures for PWID, in the European Union (EU). In the context of ending the HIV-AIDS epidemic and eliminating viral hepatitis as a public health threat, core epidemiological indicators collected from PWID are of interest to monitor the progress. Furthermore, monitoring of key interventions to identify gaps and areas where intensified efforts are needed is critical to making progress towards the sustainable development goals related to HIV and viral hepatitis.

How to use this technical protocol

This technical protocol outlines the key steps and considerations to be taken when deciding whether and how to set up a survey for monitoring DRID, related risk factors and preventive interventions among PWID. The most suitable survey approach will depend on the specific context, needs and data gaps in a country or a specific setting. Therefore, a variety of options, as well as their advantages and disadvantages, are listed in each of the sections of this protocol. In addition, best practice examples from European countries are included to serve as practical examples of the various survey steps. In each of the sections, there are links to relevant documents, protocols and literature in the *further reading* boxes, if more detailed information is required.

Update and distribution of the technical protocol

This protocol is based on the DRID toolkit (EMCDDA, 2013). It has been updated through a synthesis of evidence-based methodologies, and in a collaborative effort involving the EUDA, two consultants and a European expert group with expertise in epidemiology and observational studies among PWID. This protocol will be available on the EUDA website, and shared with the DRID network for wider distribution. Through the option of including new best practice survey examples, this protocol will be a living document, ensuring that the newest methods from surveys in the EU/EEA are included. This technical protocol will be updated as necessary to reflect changes in the evidence base, available methods and interventions.

([1]) The European Monitoring Centre for Drugs and Drug Addiction became the European Union Drugs Agency in July 2024.

Aim and objectives of the technical protocol

The main aim of this protocol is to assist EU/EEA Member States in planning and developing surveys for standardised monitoring of the prevalence of DRID among PWID, as well as risk factors and preventive interventions, on local, regional or country levels.

Steps in planning and implementing a survey

Depending on the survey objectives, study population, sampling and recruitment methods, the steps to be carried out while implementing a survey will differ. The context and needs in a country or setting will determine which approach is most suitable. It is also important to note that the feasibility of implementing the suggestions or best practice examples will depend on the context.

Points to consider when planning a survey

When planning a survey among PWID there are some initial points to consider which may also define which study design, sampling and recruitment methods will be most suitable.

Assessing available evidence and needs for the survey

A review of the available information is necessary to decide on the focus and objectives of the survey. Possible sources of information include surveillance reports (including reports from the European Centre for Disease Prevention and Control (ECDC), the EUDA and the WHO), and available publications on national, regional or local level. Moreover, the need to report DRID to the EUDA ([2]) should be considered as well as the gaps that can be filled through data collection in the survey.

Defining clear objectives for the survey

Depending on the public health needs, as well as research gaps and missing information for public health action and reporting to the EUDA, the objectives and research questions should be clearly defined. This goes in line with defining both the outcomes for which data will be collected and analysed, and the study population, for example, PWID enrolled in opioid agonist treatment (OAT) or other harm reduction services.

Examples of the objectives for a survey among PWID to collect DRID data could be to:

- estimate the prevalence of DRID among PWID;
- identify main risk factors and preventive behaviours among PWID;
- assess the access to testing and treatment of DRID;
- collect data on the core indicators for national and international reporting.

Identifying possible partners and stakeholders

It is important to build partnerships and to ensure that the survey will cover the needs of the main stakeholders, particularly the target population. Involvement and inclusion of stakeholders and partners range from input and expertise in the planning of the survey to the reporting of results. Depending on the country and local context, the most suitable

([2]) The indicators to be reported to the EUDA can be found in Table 13.

stakeholders and partners may differ. In Table 1, possible partners and ideas for their role and input are listed.

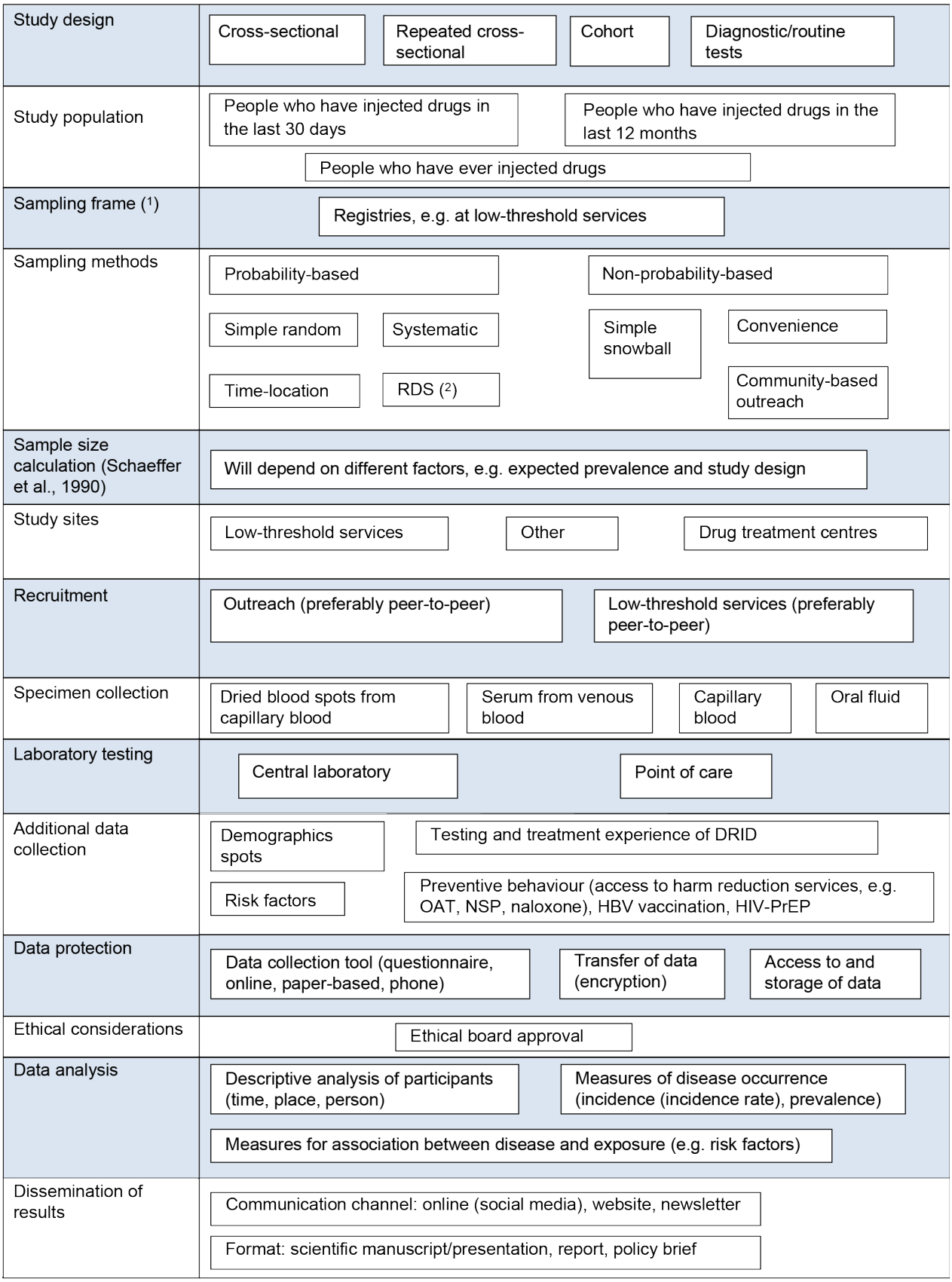
Table 1: Possible partners and stakeholders

Possible partners	Ideas for their role/input
Governmental agencies	Awareness-raising, policy input and dissemination of survey results
Non-governmental organisations	Awareness-raising and policy input, sampling, recruitment, study site and dissemination of survey results
Low-threshold services	Awareness-raising, sampling, recruitment, study site and dissemination of survey results
Peers from target population (PWID)	Awareness-raising, sampling, recruitment and dissemination of survey results
Clinical or medical sites (e.g. OAT sites)	Awareness-raising, sampling, recruitment, study site and referral to care (treatment)
Universities and research organisations/institutes	Awareness-raising, recruitment, methodological support and writing as well as dissemination of survey results

Conducting the study – from defining the study population to reporting the results

In the following sections the steps in planning and implementing a survey, as illustrated in Figure 1, are described. Importantly, the concept of *data for action* needs to be embedded in all stages of the process; from planning to implementation and reporting of results.

Figure 1: Steps in planning and implementing a study



(1) Sampling frames (a list including the entire target population; see more under Sampling and recruitment methods) are often not available for PWID.

(2) RDS is based on non-probability sampling but probability-based estimates can be derived from it.

Study designs

There are different study designs available, and the one most suitable will depend on the aim and objectives of the survey. It will also depend on the available resources (time and personnel), existing structures and collaborations for recruitment, and study sites. Different study design options, which indicators can be collected and the advantages and disadvantages of the different study designs are presented in Table 2.

The combination of data sources, either survey data and administrative data, or data entirely based on administrative data, are often referred to as record-linkage (McLeod et al., 2021; Yeung et al., 2022). Although this is not a study design in itself, it is an increasingly cost-effective approach that can be incorporated into any study design. This approach involves linking data records from different data sources using a unique data identifier. Through this approach prevalence can be estimated, and risk and preventive factors can be reported (if the data are available). The challenge of this approach is that it needs secure access to databases that might not be directly under the control of the study team. If there is no funding for a larger survey, this is a good option to ensure sustainability for continuous monitoring.

Table 2: Study designs for PWID surveys

Study design	Description	Indicators	Comments (costs, feasibility)	Advantages	Disadvantages	Best practices/ examples
Cross-sectional study	An observational study in which the disease and other variables of interest are measured at a single point in time.	Prevalence, risk and protective factors (odds ratio (OR)).	Can be set up with relatively few resources.	Not expensive, measurements conducted at one point in time.	A snapshot of the current situation, no time component or information on order of events. There is a risk that people with long duration of either DRID or IDU are over-represented, and those with short duration under-represented.	Germany: DRUCK 1, DRUCK 2.0
Repeated cross-sectional study	Same as cross-sectional study but with repeated measurements at more than one point in time if set up with comparable methods. Differs from cohort study as it does not necessarily involve the same participants.	Incidence, prevalence, risk factors and preventive behaviour (OR, relative risk (RR)).	Can be set up with relatively few resources.	Allows to discover trends (since repeated measurements) and therefore includes the time component.	Need to organise a system to ensure that people who participate more than once can be identified, e.g. through a unique data identifier.	Greece: ARISTOTLE, ARISTOTLE HCV-HIV, ALEXANDROS Scotland: Needle Exchange Surveillance Initiative (NESI)
Cohort study	An observational study where a cohort is followed over time.	Incidence, prevalence, risk factors and preventive behaviour (RR).	Usually more costly than cross-sectional surveys since the cohort is followed over time.	Possible to collect continuum-of-care data, and it includes the time component.	More resource intensive (financially and personnel/time wise). There is also a need to ensure continuous participation in the cohort and minimise drop-out rate.	Sweden: HCV care with a needle and syringe programme (NSP) clinic in Stockholm (registry based, open cohort study).

Study design	Description	Indicators	Comments (costs, feasibility)	Advantages	Disadvantages	Best practices/ examples
Routine diagnostic testing	Observational, routine diagnostic tests performed in either clinical, OAT, prisons or low-threshold settings.	Positivity rate as proxy for prevalence.	Not very costly and data readily available. If resources are available for any of the other methods, routine diagnostic testing is **not** recommended for estimating prevalence. To be considered a potential valid estimation method for prevalence, minimum requirements include: (1) identification/removal of duplicates; (2) description of source population (who gets tested? Why?).	If no funding is available for a larger survey, this is a good option. Sustainability might be easier to ensure if continuous monitoring using these data is established. Using diagnostic tests from routine testing data can also ideally be linked with treatment and other administrative data.	Will represent a certain sub-population who attend these settings, who may be at lower or higher risk of DRID, depending on services. Since this approach is not based on any sampling strategy, there is also a high risk of selection bias depending on the testing coverage of PWID in the respective settings, as well as duplicates. As already available data will be used, there is little to no control over data collection, including any additional indicators to be collected through e.g. a questionnaire.	Sweden: HCV care with a needle and syringe programme (NSP) clinic in Stockholm.

Defining the study population

The study population is a sub-population of the target population of the survey. When selecting and defining the study population, it is important to go back to the objectives and consider what the results should be used for and which target population one wants to report on. In the context of HBV, HCV and HIV those with the highest risk are people with a more recent history of injecting drug use: those reporting injecting drug use in the last 30 days or in the last 12 months.

For the purpose of monitoring at European level, the EUDA uses the following definition for PWID: people who have injected any psychoactive substance(s) not according to medical prescription ([3]) in the last 12 months.

There are, however, different options, and if a survey or study is already running, or has been set up, it may be difficult to change the definition. In Table 3 some options to consider are listed.

While most surveys and surveillance studies focus on either people who have injected in the last 12 months, or ever-injectors, local needs and context may require changing the definition of the study population. You may target certain sub-populations and add inclusion or exclusion criteria to narrow down the study population. The setting of recruitment may also impact the specific sub-population that is reached. For example, if recruitment takes place in specific settings, such as OAT services or other harm reduction services, the drug use and risk patterns of the included population may differ accordingly.

Table 3: Definition of study population

Definition	Comments
Recommended	
People who have injected drugs in the last 12 months (recent PWID)	This definition includes recent drug injectors and corresponds to the EUDA definition – those at higher risk for new infections compared to, for example, ever-injectors. They might also have a lower median age than ever-injectors. Note that people who have injected drugs in the last 30 days are included in this group.
Other options	
People who have injected drugs at some point in their life (ever PWID)	This definition will include all people who have ever injected drugs, and is likely to include a sub-group with a higher median age and lower risk of DRID, who may no longer be at increased risk of DRID. Furthermore, this group might include a higher proportion of people living with HIV (PLHIV). Note that people who have injected drugs in the last 12 months and in last 30 days are included in this group.
People who have injected drugs in the last 30 days (current PWID)	This definition will include those currently injecting drugs and those at high current risk. This is an important sub-group for specific questions on current risk/prevention behaviours.

([3]) For example, patients who are safely injecting medicines based on a medical prescription are not included.

There can also be a need to expand the definition of the study population in the case of a specific population being particularly represented in a certain area or study site. Stratifying according to the use of certain substances, irrespective of mode of transmission (e.g. crack users or non-injecting opioid users), may also be of interest in some settings.

Stratification of data can provide an overview of the situation among sub-populations of interest: for example, those under 18 or 25 years of age, those with a migration background or who experienced homelessness or according to certain geographical locations (or urban versus rural areas).

Sampling, recruitment and study sites

For surveys targeting PWID there is often an overlap between the sampling, recruitment and study sites. This is because a sampling frame is usually not available in its purest form as a list from which a sample can be drawn. In the sections below, these steps are described with examples and suggestions on how to plan and carry out the sampling and recruitment, as well as which study sites would be suitable for PWID surveys.

Sample size calculation

The sample size calculation incorporates the requirements of statistical precision into the planning of the sampling. Different pre-set parameters are required for this, and generally reflect plausible assumptions about the true state of the underlying population. These pre-settings in turn affect the sample size and the precision of your estimates.

If the purpose of the survey is to measure prevalence, then an expected prevalence is needed for the sample size calculation, among other parameters. However, often more than one disease is the focus of a survey, and the expected prevalence of different diseases generally differ. As an example, if you look at HCV prevalence exclusively, you can include the expected HCV prevalence. However, if you simultaneously include HBV, HCV and HIV in your survey, sample size calculation may depend on the expected prevalence of all three diseases. The recommended approach is to calculate the required sample size for each given prevalence/disease, then base the further planning of the survey on the maximum of all the three calculated sample sizes (if resources are available). Overall, a smaller sample size means poorer precision.

The way the sample size is calculated also depends on the primary objective of the study. If the aim is to estimate prevalence (simple proportion), the following sample size formula should be used.

Simple proportion:

- the required sample size n
- the design effect (d_{eff}) (to account for errors associated with sampling, a simple random sampling will have a lower design effect (if random sample: 1, for RDS minimum 2, preferably 3 or 4))
- the population size N
- the assumed proportion p
- $q = 1 - p$

- the desired absolute precision or absolute level of precision d

$$n = d_{\text{eff}} \times \frac{Npq}{\frac{d^2}{1.96^2}(N-1) + pq}$$

To get a rough estimate and idea of the sample size needed for further planning of the survey, the open source 'OpenEpi' can be used. The sample size can also be calculated using statistical software. The command/code for STATA and R are listed in Table 4.

Table 4: Sample size calculation formulas

STATA command	R code

power oneproportion .009 .018, p(.8)
 	
(if expected prevalence is 0.9 %, upper CI is 1.8 % and power is 80 %) ([1])
	required <- function(N=Inf, p=0.05, d=0.01, alpha=0.05, deff=1){
	q = 1-p
	z = qnorm(1-alpha/2)
	if (is.infinite(N)){
	n = deff * p*q/(d^2/z^2)
	}else{
	n = deff * N*p*q/(d^2/z^2 * (N-1) + p*q)
	}
	return(ceiling(n))
	}

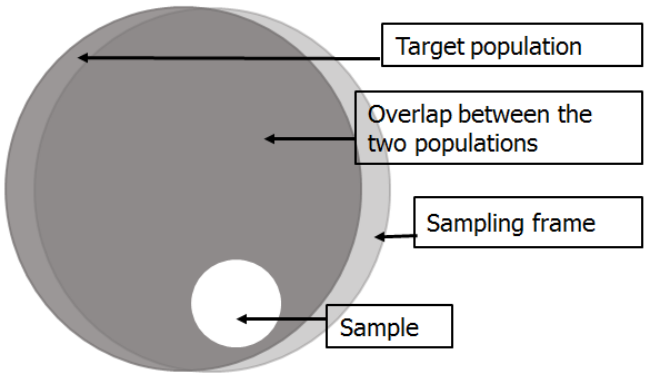
([1]) This STATA command does not include the number for the background population, but the other assumptions are included (and running in the background).

When carrying out and planning the survey, some caution must be exercised when the population size is small. In such cases, the precision might be lower. Further, if stratification is planned, for example, between males and females, the precision might change. This is particularly important among PWID, where the proportion of males is often larger than that of females.

Sampling and recruitment methods

Overall, there are two main sampling methods used in surveys: probability-based and non-probability-based sampling. For probability-based sampling each member of the target population needs to have a known probability of being selected as a study participant. The most common approaches for probability-based sampling include simple random sampling, systematic sampling, stratified sampling and clustered sampling. To generate a probability-based sample, a sampling frame is required, which is a list that includes the whole target population from which the sample will be drawn (Figure 2). The sampling frame needs to be well defined and accessible for drawing the sample.

Figure 2: Target population and sampling frame in survey sampling



Source: http://www.theanalysisfactor.com/target-population-sampling-frame/

For surveys including PWID, a registry in which the whole target population is listed is usually not available, and alternative sampling frames need to be identified. This can, for example, be the low-threshold services through which PWID are invited to take part when attending the services. However, if there is a registry available in the low-threshold service (or other institutions), this can be the sampling frame and one can draw a random or systematic sample from this registry and invite those people to participate, keeping in mind that the results are generated only for those attending this respective service.

However, while PWID are a diverse group, they share certain characteristics which can make it difficult to sample and recruit PWID for surveys. These include, for example, distrust in systems and researchers collecting data, as well as problems of inclusion (not included in official statistics or perhaps homeless/seldom at home) (Collier et al., 2017; Léon et al., 2016). Therefore, alternative sampling and recruitment methods, mostly based on harm reduction services, including outreach and through peer-to-peer sampling and recruitment, are often more suitable for PWID (Tables 5 and 6).

Table 5: Probability-based sampling methods

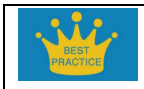
Sampling method	Description	Advantages	Disadvantages
Service, venue-based sampling	This is a pragmatic approach where existing services for PWID such as NSP, OAT and other venues are used for sampling. These are accessible for PWID, and have high coverage. This method can provide a probability-based sample, if a systematic approach is used, e.g. every 10th visitor is included.	Logistically simple as existing structures are used. Can be conducted at low cost which will help ensure sustainability.	The sample may not be representative of the whole PWID population, as those attending services might be different to those not attending. Whether or not it is considered representative depends on how the study population is defined (Sampling, recruitment and study sites). If services and venues have poor coverage and are not well-accepted, the study may be inefficient. It can be challenging to record non-response.
Time-location sampling	This approach is also sometimes referred to as time-space-sampling, and has the same principles as the methods above, but more randomly defined for reaching individuals in places and at times where they gather. If a thorough mapping is done of times/places to serve as a sampling frame, a probability-based sample can be achieved.	If the assumptions of this method are met, it is the most effective method for obtaining a probability-based sample of PWID who can be located at venues.	There is a risk of bias if important sites are not included, or if subpopulations are not frequenting the sites, or due to reluctance (disqualification due to intoxication) to participate at venues. Difficulties in identification of target group members to be approached. Difficulties in interviewing, testing or collecting biological specimens outside of a study site; there may be potential safety concerns. Weather is also a factor to consider. Reluctance to disclose sensitive information in public spaces. PWID who do not gather or meet in public are usually missed.
Respondent-driven sampling (RDS) ([1])	This is a modified chain recruitment method, similar to snowball sampling, but is based on a set of assumptions and works with incentives. If assumptions are met it is a probabilistic sampling method and will ensure an unbiased estimate.	Controlled conditions at study site. Efficient. Potential to reach the most hidden population and reach deeper into the network through well networked and dedicated seeds. Through repeated RDS rounds it can be possible to increase the number of participants. It offers a way to correct for network sampling biases, and to generate unbiased estimates of the population characteristics.	Higher cost (incentives, costs of hiring the recruitment place – if conducted through a new site and not an already existing setting – staff intensive). Bias resulting from not meeting the RDS assumptions. Disconnected sub-groups may be missed, and the population being recruited must be well connected with one another as members of the target population. Large design effect (minimum 2, preferably 3 or 4) which will lead to a larger sample size.

([1]) RDS is based on non-probability sampling but probability-based estimates can be derived from it.

Table 6: Non-probability-based sampling methods

Sampling method	Description	Advantages	Disadvantages
Snowball sampling	This is a non-probability-based sampling method through which PWID who take part in the survey are asked to sample and recruit further participants through their network. Not very stigmatising.	Efficient. Potential to reach the hidden subpopulations without stigma.	There is a risk of selection bias (recruitment depends on the personal networks of the peers leading to over- or under-representation of certain groups or characteristics in the sample). Individuals who are more likely to and willing to take part will be over-represented.
Community-based outreach sampling (*convenience sampling*)	This is a non-probability-based method, but a good way to sample the target population where they are using peer-to-peer sampling/recruitment.	Through this approach you can reach the more hidden group of PWID. Specific marginalised groups can be targeted (more than through snowball sampling).	This is a non-probability-based sampling approach and there is a risk of selection bias which cannot be estimated nor adjusted for in the analysis. Non-response cannot be recorded.

The most acceptable sampling and recruitment strategy will depend on the target population, the overall context and the country or city in which the survey is carried out. During this step, input from local stakeholders and representatives from the target population on where and how to sample and recruit the target population will be very useful. One way of collecting this information before starting the survey is to conduct formative research, including focus group discussions and interviews.



Best practice example: Respondent-driven sampling in several multiple rounds, Greece

RDS in several multiple rounds will allow you to reach deeper into the network and it also boosts enrolment to reach a larger proportion of the target population. It also makes it possible to assess changes or trends over time, estimation of incidence and facilitates linkage to HIV/HCV care (read full example from Greece here).

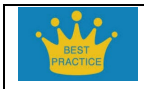
Further reading 

Schaeffer, R., Mendenhall, W. and Ott, L. *Elementary survey sampling, fourth edition*, Belmont, California (1990).

World Health Organization. Regional Office for the Eastern Mediterranean, *Introduction to HIV/AIDS and sexually transmitted surveillance. Module 4: Introduction to respondent-driven sampling* (2013).

Motivation for participation

Incentives may be useful in order to increase the motivation for participation. Material incentives can include cash payment, vouchers, small gifts and coverage of travel costs. Providing participants with the results of laboratory testing and referral to clinical care may also encourage people to participate. For snowball sampling, an incentive can be provided per recruited participant. In RDS, incentives for both participants and recruiters is a common part of the method. Also, recruitment through peers may be an efficient way to reach and recruit PWID. This can be done via RDS, where recruiters from the target population recruit members of their peer network. This might enable the study to reach deeper into the community, reaching more isolated members of the target population (Collier et al., 2017). It is advised to choose initial recruiters ('seeds') who are diverse in their characteristics (e.g. gender, age, HIV status, risk behaviour, etc.) (WHO, 2013).



Best practice example: Respondent-driven sampling and incentives, DRUCK, Germany

RDS is efficient, but is mostly associated with a higher workload and costs. In Germany (DRUCK 1), PWID were offered EUR 10 for participation and an additional EUR 5 per recruited participant. For DRUCK 2.0, convenience sampling was used, including an EUR 10 incentive for participation. The RDS sample and the convenience sample were found to be broadly similar, with few differences between them. Therefore, for future monitoring surveys, convenience sampling will be used (read full examples from DRUCK 1 and DRUCK 2.0 from Germany here).

Recruitment and study sites

There are several options for study sites to be used for data and specimen collection. The selection of the study site most appropriate for the survey will depend on the local context and overall study design, including the selected sampling and recruitment methods. Moreover, it depends on what sites are available at local or national level, their capacity and willingness to take part in a survey, and whether there is already a good working relationship.

The study sites can be used as the sampling frame but also for recruitment of the study population (described in more detail in Sampling and recruitment methods). Sampling and recruitment, which for general population surveys are mostly separated (ECDC, 2020), are often one step and make use of the same setting in PWID surveys. There are different advantages and disadvantages with the various options for recruitment and study sites. It is important to consider this choice and its impact on the study population, as, for example, the characteristics of a sub-group of the study population attending a drug treatment centre (if this is selected as the recruitment site) may differ from those attending drug consumption rooms. The most suitable study site will often also depend on which study population is targeted.

A number of general aspects to consider before selecting recruitment and study sites are listed in Table 7.

Table 7: Considerations for selecting study and recruitment sites

Aspects to consider	
Room(s)/space available at the site	A sufficient number of rooms need to be available at the study site (for waiting and collection of biological samples, completion of questionnaire, storage of biological samples), particularly when setting up a study with fixed participation hours.
Accessibility	Consider the accessibility of recruitment and study sites in terms of opening hours, proximity, ease of finding and reaching with public transport.
Acceptability	Study and recruitment sites need to be well accepted places for the study population. This includes that they are sensitive in terms of different cultures and languages, and also that they provide a safe space in terms of stigma, discrimination and criminalisation.
Clients attending and visiting the service	This could be specific sub-populations, e.g. patients in OAT; PWID making use of NSP (see also Table 8).
Resources available	Including staff, knowledge and capacity to recruit and include participants.

Table 8: Recruitment and study sites (as per EUDA reporting in FONTE)

Study sites	Advantages	Disadvantages
Drug treatment centres (in- and outpatient)	PWID are in contact with a service already, making contact and recruitment easier. A medical team is available for counselling and invasive procedures (venous blood drawing).	Will only be able to recruit a sub-sample of PWID; those attending drug treatment centres may not be at highest risk of DRID.
Drug treatment centres (OAT)	PWID are in contact with a service already, making contact and recruitment easier. A medical team is available for counselling and invasive procedures (venous blood drawing).	Will only be able to recruit a sub-sample of PWID; those attending drug treatment centres may not be at highest risk of DRID.
Drug treatment centres (unspecified)	PWID are in contact with a service already, making contact and recruitment easier. A medical team is available for counselling and invasive procedures (venous blood drawing).	Will only be able to recruit a sub-sample of PWID, those attending drug treatment centres may not be at highest risk of DRID.
Needle and syringe programmes (including outreach)	PWID are in contact with a service already, making contact and recruitment easier.	Will include a specific sub-sample of the target population of active injecting drug users and thereby higher risk and perhaps higher prevalence. On the other side, they are presumably mostly consuming drugs through NSP.
Drug consumption rooms	PWID are in contact with a service already, making contact and recruitment easier.	Will include a specific sub-sample of the target population of active injecting drug users and thereby higher risk and perhaps higher prevalence. However, PWID attending this service are consuming drugs in a safer environment compared with the street, with possibly unsterile/shared injecting equipment.
Other low-threshold services (including outreach)	PWID are in contact with a service already, making contact and recruitment easier.	Will include a specific sub-sample of the target population of active injecting drug users and thereby higher risk and perhaps higher prevalence. However, PWID attending these services could be consuming drugs in a safer environment compared with the street.

Study sites	Advantages	Disadvantages
STI clinics	A good infrastructure for testing for DRID. A medical team is available for counselling and invasive procedures (venous blood drawing).	Will include a higher proportion of people who do not use drugs and, if recruitment is done in this setting, it may be more challenging to reach the sample size. Depending on the context, it may be more difficult for participants to openly share information about past or current drug use.
Voluntary counselling and testing (VCT) centres	A good infrastructure for testing for DRID.	Will include a higher proportion of people who do not use drugs and, if recruitment is done in this setting, it may be more challenging to reach the sample size. Depending on the context, it may be more difficult for participants to openly share information about past or current drug use.
General practitioners	Electronic database type of study (when there is the possibility to identify drug users in the registries and link them with other information). A good opportunity for increasing the importance and awareness of DRID for general practitioners. A medical team is available for counselling and invasive procedures (venous blood drawing).	Will include a higher proportion of people who do not use drugs and, if recruitment is done in this setting, it may be more challenging to reach the sample size. Depending on the context, it may be more difficult for participants to openly share information about past or current drug use.
Emergency departments in hospitals	A good infrastructure for testing for DRID. A medical team is available for counselling and invasive procedures (venous blood drawing).	Will include a higher proportion of people who do not use drugs and, if recruitment is done in this setting, it may be more challenging to reach the sample size. Depending on the context, it may be more difficult for participants to openly share information about past or current drug use.
Prisons	A closed environment with the likelihood of high participation rate as there is a large overlap in many countries between current or past drug use and imprisonment. Good options for linkage to care and retention in treatment.	This will include a specific sub-sample of the population which are likely at higher risk of DRID.
Street recruitment	Peer to peer recruitment in the streets may result in higher participation and more acceptance.	If RDS it may be cumbersome and difficult to adjust in the analyses later on, and more organisation of questionnaire and data collection needed if there is no physical study site.
Sites opened for purpose of the study	Setting up sites specifically for the study allows complete flexibility, and can be arranged and adjusted according to the study needs (space, opening hours, etc.).	There may be an issue with sustainability after funding for a survey ends. There will be now already known information about what people might be reached for the survey. There will not be any already existing trust or knowledge of the existence of the site.

Specimen collection and testing

There are different ways of testing for HIV and viral hepatitis, and which is more applicable will depend on context, study site and target population. Most importantly, you need to consider the costs and the information required for monitoring. In the case of HCV, a positive antibody test will require additional testing for viraemic infection. However, if the survey is

conducted among a population with a high expected viraemic prevalence (>70 %), only HCV RNA testing might be warranted, or HCV core antigen, depending on the financial resources available for the survey. If there is no funding available for HCV RNA testing, the samples could be stored to allow retrospective testing for HCV RNA at a later point in time when (or if) funding becomes available.

The types of tests available, their use and interpretation along with their advantages and disadvantages are listed in Table 9. The European Association for the Study of the Liver (EASL) and WHO provide detailed recommendations for HBV and HCV testing, including the type of test and laboratory procedures (see *Further reading* box).

The markers and how to interpret these are listed in Tables 10, 11 and 12.

Table 9: Testing biological material for hepatitis B, hepatitis C and HIV – available tests by sample type (applies for PWID in low-threshold settings, including outreach)

Biological material	Tests available	Advantages	Disadvantages
Serum/plasma (from venepuncture), sent to a laboratory for testing	All serological and molecular tests for HBV, HCV, HIV	Good sensitivity All tests and markers possible No problem of insufficient amount of specimen for all tests Residual serum can be stored for further studies	Might be more challenging than dried blood spots (DBS) if the veins are damaged In some countries, medical personnel are needed to draw blood samples. More invasive procedure compared to DBS
Dried blood spots (from capillary blood), sent to a laboratory for testing	All serological and molecular tests for HBV, HCV, HIV For determining HBV vaccination status, the sensitivity of anti-HBs from DBS might be reduced (depending on the laboratory validation)	Easy to use 'in the field', and does not require specific staff. After training and practice it works well. If poor vein access due to drug use, finger pricks might be a good alternative	If more markers need to be tested, many spots might be needed which can be a challenge (to get enough blood from the fingers) Testing from DBS is not validated for diagnostic testing by the manufacturers
Whole blood (from venepuncture or capillary blood from finger prick) for testing at study site	Rapid testing HBs antigen; anti-HCV, HCV-antibody/antigen, anti-HIV, HIV-antibody/antigen p24 PoC PCR for HCV, HIV	Quick result Can be delivered at point of care (PoC) to improve access to testing and treatment	May be less sensitive (need to meet minimum performance standards) For HCV, confirmatory PCR testing is needed to determine if it is a viraemic infection PoC PCR is expensive
Oral fluid to be tested at a study site	HBV HBs antigen test (also with saliva) HCV Rapid HCV antibody tests Laboratory HCV test (also with saliva) HIV Rapid HIV antibody test, laboratory-based screening assays Laboratory-based western blot	A non-invasive method which is easy to use in any setting	Lower sensitivity than other specimens Depending on oral hygiene this may be a method less accepted among the target population compared to blood sample. The detection window may be shorter, and in some countries, saliva tests are not recognised as diagnostic tests due to the lower sensitivity

For HBV, the markers are often tested concurrently, and the test result will inform whether an infection is acute or chronic, what stage of disease the person is in, and what treatment the person will need and benefit from (WHO, 2017).

Table 10: Minimum, recommended and optional HBV markers and interpretation

	HBV marker		**Interpretation**
Minimum	HBsAg	HBsAg positive	Viraemic (acute or chronic) infection
Recommended	HBsAg Anti-HBc Anti-HBs	HBsAg positive, Anti-HBs negative, Anti-HBc positive	Chronic infection
Optional	HBsAg Anti-HBc Anti-HBs	HBs-Ag negative, Anti-HBs positive, Anti-HBc positive	Past HBV infection
Optional	HBsAg Anti-HBc Anti-HBs ([1])	HBs-Ag negative, Anti-HBs positive, Anti-HBc negative	Vaccinated against HBV
Optional	HBV DNA	HBV DNA present (VL to determine treatment indication)	Viraemic infection

([1]) Anti-HBs is only recommended as a marker to be tested for in venous blood samples. This is due to (1) the high threshold for detection when testing from DBS due to the dilution step and (2) the waning immunity, in particular after childhood vaccination. Anti-HBs from DBS might lead to underestimation of the proportion being vaccinated.

Table 11: Minimum and recommended HCV markers and interpretation

	HCV marker	**Interpretation**
Minimum requirement	HCV RNA (HCVcAg) positive	Viraemic infection
Recommended	Anti-HCV positive, HCV RNA (or HCVcAg) positive	Proxy for chronic infection ([2])
Recommended	Anti-HCV negative, HCV RNA (or HCVcAg) positive	Recent viraemic infection
Recommended	Anti-HCV positive (to be confirmed with blot) ([1]), HCV RNA (or HCVcAg) negative	Past (cleared) infection

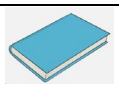
([1]) A reactive anti-HCV screening test (e.g., ELISA, PoCT) result should be confirmed with a second test due to false reactive test results (reduced specificity). If an RNA/cAg test is negative, anti-HCV immunoblot should be applied.

([2]) World Health Organization (2018), *Consolidated strategic information guidelines for viral hepatitis: planning and tracking progress towards elimination*, World Health Organization, Geneva.

Table 12: Minimum, recommended and optional HIV markers and interpretation

	HIV marker	Interpretation
Minimum	Anti-HIV ([1])	HIV positive, needs confirmatory testing
Recommended	HIV RNA through PCR	HIV positive and viral load (undetectable if receiving antiviral treatment)
Optional	Anti-HIV followed by immunoblot if anti-HIV is positive	HIV positive

([1]) If a 4th generation HIV test is used, it will provide results for HIV1, HIV2 and the p24 antigen, which decreases the diagnostic window from 3 months to 6 weeks.

Further reading 

- ECDC, Public health guidance on HIV, hepatitis B and C testing in the EU/EEA (2018).
- WHO, Consolidated guidelines on HIV testing services (2015).
- WHO, Guidelines on hepatitis B and C testing (2017).
- WHO, Updated recommendations on simplified service delivery and diagnostics for hepatitis C infection (2022).

Data collection, management and analysis

Data collection

A questionnaire should be used to collect additional information from the survey participants. Basic socio-demographic information, such as sex or gender, age, education, migration status and living conditions, should always be collected. Additional PWID information on risks (e.g. drug consumption, sharing of drug paraphernalia, unsafe sex, imprisonment), preventive measures (e.g. provision with sterile equipment for drug use, access to OAT, naloxone, HIV-pre-exposure prophylaxis (PrEP) and vaccination), history of testing for infectious diseases and treatment history should be collected, preferably according to the EUDA core indicators (see list of indicators in Table 13 and template questionnaires (short and extended versions)). The specific content of the questionnaire should be linked to the survey aim and kept short in order to increase response rate. If needed, the questionnaire should be made available also in simple language and possibly translated into other languages relevant for the target population.

It is a good idea to validate and pre-test the questionnaire, and also to ask a representative from the target population to review the questionnaire to ensure that the content is well-understood, to improve validity. Importantly, if the questionnaire is translated, the language should be proof-read by a person speaking the native language to verify the translation and ensure that the translation has the same meaning as intended in original language. The most important questions should be placed at the beginning of the questionnaire.

The questionnaire can either be paper-based or online (to be completed, for example, on a tablet), and can be self-administered or completed with the help of interviewers or service staff. If interviewers or service staff are involved, they should be trained for the task,

especially if the questionnaire includes sensitive questions. It is important to ensure that each participant's questionnaire responses and diagnostic test results can be linked.

Data management

For data management, programmes for the entry and checking of data should be developed, for example using EpiData Software (Christiansen and Lauritsen, 2010). Two databases should be created, one for the laboratory data and one for the behavioural data collected through the questionnaire. If the questionnaire is completed on paper and afterwards entered into a database, double entry of data is considered best practice and should be where possible to check for discrepancies. The final dataset can then be produced. The data can be entered directly into a database if data are collected electronically at the time of the interview. An electronic questionnaire allows skips and logical checks which improve data quality. After the end of data collection, the two databases should be merged using the participant ID (a unique participant identifier). Then the data can be imported into statistical software.

Data analysis

It is important to use the appropriate analyses considering the design and sampling and recruitment methods used in the survey. Survey weights can be used to account for unequal probabilities of selection into the sample focusing on key variables. As an example, if more people of younger age were included in the sample compared to the original distribution in the target population, PWID of older age can be given more weight in the analysis.

Usually, in epidemiological surveys of PWID, the following DRID estimates include:

- different measures for frequency of disease (incidence and prevalence)
- different measures for association between disease and exposure (either risk or preventive factors)

Moreover, PWID are often exposed to various risk environments such as incarceration, homelessness or sex work, which may all increase the risk of exposure to blood-borne viruses. Further, age, gender and types of drugs used may impact the exposure to and effect of the risk environment (Degenhardt et al., 2017; 2023). Therefore, this is also valuable information to collect when carrying out a PWID survey, and it can be used to stratify the data analysis in order to generate detailed data for action and to enable a targeted response.

The indicators that are core, recommended and optional are listed in Table 13.

Table 13: Indicators of disease occurrence, risk factors and interventions among PWID

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
Burden and impact	Prevalence of HBsAg	Core	Proportion of PWID who tested HBsAg-positive	Number of PWID who tested HBsAg-positive	Number of PWID tested within the study (total population)	Cross-sectional or cohort study with biological sample
	Prevalence of viraemic HCV infection	Core	Proportion of PWID with viraemic HCV infection (HCV RNA positive or HCV-Ag positive)	Number of PWID who tested positive for HCV RNA or HCVcAg	Number of PWID tested within the study (total population)	
	Prevalence of anti-HCV (ever-HCV infected)	Core	Proportion of PWID with positive anti-HCV	Number of PWID who tested anti-HCV positive	Number of PWID tested within the study (total population)	
	Prevalence of viraemic HCV infection among ever-infected	Optional	Proportion of viraemic HCV infection over those ever infected	Number of PWID who tested positive for HCV RNA or HCVcAg	Number of PWID who tested positive for anti-HCV	
	Prevalence of recent HCV infection	Optional	Proportion of PWID anti-HCV negative and HCV RNA/HCV-Ag positive	Number of PWID who tested anti-HCV negative and HCV RNA/cAg positive	Number of PWID tested within the study (total population)	
	Prevalence of HIV infection	Core	Proportion of PWID living with HIV infection	Number of PWID who tested HIV positive (confirmed)	Number of PWID tested within the study (total population)	
	Incidence of HCV infection	Optional	Incidence rate of new infections with HCV (HCV RNA/cAg+)	Total number of new infections with HCV (HCV RNA/cAg+) in a given time period	Total population minus people living with hepatitis C (HCV RNA/cAg+) (person time at risk)	
	Incidence of HCV re-infection	Optional	Incidence rate of re-infections with HCV (HCV RNA/cAg)	Total number of new infections with HCV (HCV RNA/cAg+) among people who had cleared the infection following DAA treatment in a given time period	People who had cleared the infection following DAA treatment (person time at risk)	Cross-sectional or cohort study with biological sample
	Incidence of HIV infection	Optional	Incidence rate of new HIV infections	Total number of new infections with HIV (sero-conversion) in a given time period	Total population minus people living with HIV (person time at risk)	Cross-sectional (with modelling) or cohort study with biological sample

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
Risk factors	Prevalence of injecting with needles/syringes that were already used by others	Core	Proportion of PWID injecting with used needles/syringes in the last 30 days	Number of PWID reporting injecting with used needles/syringes in the last 30 days	Number of PWID included in the study who answered the question on using used needles/syringes	Cross-sectional or cohort data (questionnaire)
	Prevalence of using other paraphernalia already used by others	Recommended	Proportion of PWID sharing any used injecting paraphernalia in the last 30 days other than needles/syringes (using together, receiving or passing on)	Number of PWID reporting sharing used injecting paraphernalia in the last 30 days other than needles/syringes (using together, receiving or passing on)	Number of PWID included in the study who answered the question on sharing used injecting paraphernalia	Cross-sectional or cohort data (questionnaire)
	Frequency of injection in the last 30 days	Recommended	Mean/median number of injections in the last 30 days is calculated using the mean/median number of days with IDU in the last 30 days multiplied by mean/median number of injections on average consuming day in last 30 days	Number of days with IDU in the last 30 days Number of injections on an average consuming day in the last 30 days	Number of PWID who reported injecting in the last 30 days who answered both questions on number of IDU days and number of injections	Cross-sectional or cohort data (questionnaire)
	Proportion of new injectors	Recommended	Proportion of PWID who started injecting in the last 2 years is one category of number of years since first injection. This number is calculated by subtracting the age at first injection from the current age	Number of PWID who started injecting in the last 2 years	Number of PWID who answered the question on age [years] at the time of the study and the age [years] at first injection	Cross-sectional or cohort data (questionnaire)

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
	Prevalence of injecting drug use, by substance	Recommended	Proportion of PWID injecting in the last 30 days, by substance (heroin, methadone, buprenorphine, fentanyl and derivatives, benzimidazole opioids, morphine, oxycodone, tramadol, powder cocaine, crack cocaine, amphetamine, methamphetamine, synthetic cathinones, benzodiazepines, MDMA and derivatives, GHB/GBL, ketamine, others)	Number of PWID injecting in the last 30 days, by substance	Number of PWID included in the study who answered the question on substances injected	Cross-sectional or cohort data (questionnaire)
	Prevalence of past imprisonment	Recommended	Proportion of PWID who report having ever been in prison	Number of PWID with history of imprisonment	Number of PWID included in the study who answered the question on past imprisonment	Cross-sectional or cohort data (questionnaire)
	Prevalence of homelessness in the last 12 months or currently	Recommended	Proportion of PWID who lived without a steady home, on the streets or temporarily in a hostel or shelter, any time in the last 12 months	Number of PWID who experienced homelessness in the last 12 months	Number of PWID included in the study who answered the question on homelessness	Cross-sectional or cohort data (questionnaire)
	Experience with discrimination when accessing healthcare in the last 12 months ([2])	Recommended	Proportion of PWID who have experienced discrimination accessing healthcare in the last 12 months	Number of PWID who reported experience of discrimination accessing healthcare in the last 12 months	Number of PWID included in the study who answered the question on discrimination accessing healthcare	Cross-sectional or cohort data (questionnaire)
Prevention	Needle-syringe distribution	Core	Average number of sterile needles/syringes received per person who injects drugs in the last 12 months	Number of sterile needles/syringes received from NSP per PWID in the last 30 days	n.a. For this indicator we compute an average over all responses and multiply by 12 to get a yearly estimate	Cross-sectional or cohort data (questionnaire) ([3])

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
	OAT coverage	Core	Proportion of PWID consuming opioids currently receiving medically-prescribed OAT	Number of PWID receiving OAT at the time of the study	Number of PWID consuming opioids or on OAT included in the study who answered the question on OAT	Cross-sectional or cohort data (questionnaire or record linkage)
	HBV vaccination coverage ([4])	Recommended	Proportion of PWID reporting being vaccinated against HBV	Number of PWID who have received a hepatitis B vaccine	Number of PWID included in the study with information on HBV vaccination	Cross-sectional or cohort data (blood sample, questionnaire or record linkage) (data from databases or registries)
	Condom use	Recommended	Proportion of PWID reporting the use of a condom at last sexual intercourse	Number of PWID reporting the use of a condom at last sexual intercourse	Number of PWID included in the study who answered the question on condom use	Cross-sectional or cohort data (questionnaire)
	PrEP use	Recommended	Proportion of PWID who have used PrEP at least once in the last 12 months	Number of PWID who have received PrEP at least once during the last 12 months	Number of PWID included in the study who answered the question on PrEP	Cross-sectional or cohort data (questionnaire or record linkage)
	Naloxone coverage	Recommended	Proportion of PWID carrying naloxone	Number of PWID who are carrying naloxone at the time of the study	Number of PWID included in the study who answered the question on naloxone	Cross-sectional or cohort data (questionnaire)
Continuum of HIV care	Testing (HIV)	Core	Proportion of PWID who have been tested for HIV in the last 12 months (not taking into account tests done within the study and excluding those with a known diagnosis of HIV)	Number of PWID reporting an HIV test in the last 12 months (not taking into account tests done within the study and excluding those with a known diagnosis of HIV)	Number of PWID included in the study who answered the question on HIV testing (excluding those with a known diagnosis of HIV)	Cross-sectional or cohort data (questionnaire or record linkage)

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
	Diagnosis (HIV)	Core	Proportion of PWID living with HIV who know their status	Number of PWID tested positive for HIV in the study who were aware of their HIV+ status	Number of HIV+ PWID included in the study who answered the question on HIV status	Cross-sectional or cohort data (blood sample and questionnaire or record linkage)
	Treatment (HIV)	Core	Proportion of PWID diagnosed with HIV receiving antiretroviral therapy (ART)	Number of PWID who were (already) diagnosed with HIV and are currently receiving ART	Number of PWID included in the study who were (already) diagnosed with HIV with information on ART	Cross-sectional or cohort data (blood sample and questionnaire or record linkage)
	Viral suppression (HIV)	Recommended	Proportion of PWID living with HIV, and who are on treatment, achieving viral load suppression	Number of PWID who are receiving ART and currently virally suppressed	Number of PWID who were (already) diagnosed with HIV and are receiving ART	Cross-sectional or cohort data (blood sample and questionnaire or record linkage)
HBV care ([5])	Testing (HBV)	Recommended	Proportion of PWID who have been tested for HBV in the last 12 months (not taking into account tests done within the study and excluding those with a known diagnosis of HBV)	Number of PWID reporting an HBV test in the last 12 months (not taking into account tests done within the study and excluding those with a known diagnosis of HBV)	Number of PWID included in the study who answered the question on HBV testing (excluding those with a known diagnosis of HBV)	Cross-sectional or cohort data (questionnaire or record linkage)
	Testing (HDV)	Optional	Proportion of PWID who have been tested positive for HBV who have also been tested for HDV in the last 12 months	Number of PWID reporting an HDV test in the last 12 months (not taking into account tests done within the study) and excluding those that are HBV negative	Number of PWID included in the study who answered the question on HDV testing (excluding those with negative HBV test)	
	Diagnosis (HBV)	Optional	Proportion of PWID with viraemic HBV who have been diagnosed with HBV infection (who were aware of their infection)	Number of PWID who tested HBsAg+ who have been diagnosed with HBV infection (self-reported or with record of past diagnosis)	Number of HBsAg+ PWID included in the study who answered the question on HBV status	

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
	Treatment (HBV)	Optional	Proportion of PWID diagnosed with HBV infection receiving HBV treatment	Number of PWID who tested HBsAg+ who are currently receiving treatment (self-reported or with record of treatment)	Number of PWID included in the study who were (already) diagnosed with HBV infection with information on HBV treatment	
	Viral suppression (HBV)	Optional	Proportion of patients with HBV infection on treatment in whom HBV viral load (VL) is suppressed	Number of patients with HBV infection on treatment who have a suppressed VL (HBV DNA not detectable), based on VL measurement in the past 12 months	Number of patients with HBV infection on treatment and assessed for VL in the past 12 months	
HCV care ([6])	Testing (HCV)	Core	Proportion of PWID who have been tested for HCV in the last 12 months (not taking into account tests done within the study)	Number of PWID reporting an HCV test in the last 12 months (not taking into account tests done within the study)	Number of PWID included in the study who answered the question on HCV testing	Cross-sectional or cohort data (questionnaire or record linkage)
	Diagnosis (HCV) – ever	Core	Proportion of anti-HCV+ and/or HCV-RNA+ PWID who have ever been diagnosed with viraemic HCV infection	Number of anti-HCV+ and/or HCV-RNA+ PWID who have ever been diagnosed with viraemic HCV infection (self-reported or with record of past diagnosis)	Number of anti-HCV+ and/or HCV-RNA+ PWID included in the study who answered the question on diagnosis of active HCV infection (ever) (or with available records)	Cross-sectional or cohort data (questionnaire or record linkage)
	Diagnosis (HCV) – last 12 months	Core	Proportion of anti-HCV+ and/or HCV-RNA+ PWID who have been diagnosed with viraemic HCV infection in the last 12 months	Number of anti-HCV+ and/or HCV-RNA+ PWID who had a diagnosis of viraemic HCV infection in the last 12 months (self-reported or with record of diagnosis in the last 12 months)	Number of anti-HCV+ and/or HCV-RNA+ PWID included in the study who answered the question on diagnosis of active HCV infection (or with available records)	Cross-sectional or cohort data (questionnaire or record linkage)

Building block	Indicator ([1])	Core/ recommended/ optional	Definition	Numerator	Denominator	Study design (data source)
	Treatment (HCV) – ever	Core	Proportion of anti-HCV+ and/or HCV-RNA+ PWID who have ever received HCV antiviral treatment	Number of anti-HCV+ and/or HCV-RNA+ PWID who have ever received HCV antiviral treatment (self-reported or with record of treatment)	Number of anti-HCV+ and/or HCV-RNA+ PWID included in the study who answered the question on HCV antiviral treatment (or with available records)	Cross-sectional or cohort data (questionnaire or record linkage)
	Treatment (HCV) – last 12 months	Core	Proportion of anti-HCV+ and/or HCV-RNA+ PWID who initiated HCV antiviral treatment in the last 12 months	Number of anti-HCV+ and/or HCV-RNA+ PWID who initiated HCV antiviral treatment in the last 12 months (self-reported or with record of treatment initiation in the last 12 months)	Number of anti-HCV+ and/or HCV-RNA+ PWID included in the study who answered the question on HCV antiviral treatment (or with available records)	Cross-sectional or cohort data (questionnaire or record linkage)
	Sustained virological response (HCV)	Recommended	Proportion of patients with hepatitis C cured among those who completed treatment	Number of patients who completed hepatitis C treatment and had a sustained virological response (SVR) based on VL measurement 12–24 weeks after the end of treatment (in the past 12 months)	Number of patients who completed hepatitis C treatment and were assessed for SVR 12–24 weeks after the end of treatment (in the past 12 months)	Cross-sectional or cohort data (questionnaire or record linkage or blood sample)

([1]) Some of these indicators should be stratified by age, gender and exposures to risk/protective factors as needed and as indicated in the EUDA data collection tool.

([2]) Discrimination is included as a new indicator. Although our focus is on discrimination experienced in accessing healthcare, the scope of stigma and discrimination experienced by PWID is much broader. A suggestion on how to collect data on this indicator is included in the example questionnaire.

([3]) A (repeated) cross-sectional survey of distributing drug services is an alternative method to assess type and quantity of distributed drug paraphernalia and the number of supplied PWID (Hommes et al., 2023).

([4]) Self-reported data should be used (yes/no, not number of doses). Anti-HBs should only be measured in blood if venous blood samples are collected.

([5]) Given the nature of observational studies, these indicators are providing some proxy measures for some of the steps of the continuum of care but not the full continuum as defined by WHO.

([6]) Given the nature of observational studies, these indicators provide some proxy measures for some of the steps of the continuum of care but not the full continuum as defined by WHO.

Ethical considerations and data protection

Ethical approval and data protection issues need to be cleared prior to initiating data collection. It is important to initiate these steps early on as they can be lengthy processes, and survey materials may need to be amended based on the feedback received.

Data protection

All surveys carried out in the EU/EEA need to adhere to the General Data Protection Regulation. Seeking approval from the appropriate data protection commission/officer is the first step. This is important as it covers issues such as who has access to survey data, including personal and sensitive information collected either through the questionnaire or the biological samples. Information storage, recording (i.e. using personal unique identifiers) and access are key issues that need to be addressed. If data are transferred, make sure that an encrypted and secure server is used, and that no personal information (or other information that could identify an individual) is shared via email.

Ethical considerations and data protection

The survey needs to fulfil existing national rules and legislation, and ethical approval must be obtained prior to initiating data collection. Important points to consider, to ensure that the ethical standard of the survey is high, are:

- collection of written informed consent from all participants prior to participation;
- voluntary participation (and possibility to withdraw participation without negative consequences);
- ensuring data protection and confidentiality;
- importance of providing the test results to the participants, and how linkage to care is ensured for those tested positive (individual and public health benefits of the survey);
- in an unlinked anonymous testing survey, test results cannot be provided to individuals; in that case, participants should be provided with information on free regular access to blood-borne virus testing.

Logistical aspects

Funding and costs

The decisions regarding study design, sample size, sampling and recruitment methods, and size of the study team will all impact the costs of the survey and the required funding. A survey using anonymous testing is cost-saving as there is no diagnostic testing and staffing requirements are lower. To get an overview, a budget should be developed in the planning phase considering:

- planning and preparation
- sampling and recruitment of participants
- study site
- study time (size of team and required training)
- specimen/data collection

- storage and transport
- laboratory analysis
- data entry and cleaning
- analysis
- reporting/dissemination of the survey results

It may be challenging to maintain surveillance, and sustainability of funding is an important barrier for continuous surveillance among PWID. Advocating for the need for and use of data to target services, and ultimately following a cost-efficient model, is therefore important in order to secure political will and funding.

Study team and training

To ensure that the survey runs smoothly, it is important to appoint an overall project coordinator, who will also be responsible for ensuring that all the necessary steps are taken to implement the survey (e.g. data protection, ethical approval, etc.).

When carrying out a survey among PWID, and depending on the sampling and recruitment methods and study site, it is necessary to have one person on-site who is responsible for coordinating the survey and reporting any potential issues or lessons learnt back to the survey manager. It is key to involve members of the community. It is highly recommended to carry out sampling and recruitment in settings frequented by the target population, and in this process include and involve peers who know the target population. A few survey team members/tasks to consider (often one person covers more than one task) are:

- a coordinator (overall and on-site)
- persons responsible for recruitment (preferably peers and people representing the target population)
- healthcare personnel (nurses or doctors depending on type of test and delivery of test results)
- biostatistician or epidemiologist (for data management and analysis)

It is important that all staff included in the survey are well-trained. All the survey tasks and who is to carry them out should be clear and described in detail in standard operating procedures (SOPs). Depending on the size of the survey and the number of staff members involved and their roles, you may want to consider a single training session for all or separate sessions focused on a specific task.

Timeline

Regardless of the type of survey and the number of participants, it is always advisable to allow sufficient time to carry it out. Preparation and approval of data protection and ethics may take a long time, and the collaborating partners and stakeholders need sufficient time to prepare the study site for the survey. Staff need to be engaged and trained prior to the onset of data collection. Moreover, when planning the survey, depending on the sampling and recruitment methods, the timing of the survey is important. If the survey is carried out outdoors, it would be advantageous to avoid winter. Also, it is recommended to check for public holidays to ensure that services are open (and these may differ in different cities in a country). Consideration must also be given to the phase after data collection, allowing time for data analysis and reporting and dissemination of the results.

Reporting of results, plans for dissemination

How to report the results as well as how they should be disseminated is an important part of the survey. This may include the writing up of results in a manuscript to be submitted to a peer-reviewed journal, a report to the ministry of health or other stakeholders, or a presentation at a conference or a meeting with interested partners and stakeholders. It is also key to provide information on the results and implications to the collaborating partners and target population in an easily readable way and through appropriate communication channels.

Data for action should be a key element of the planning and implementation of a survey. By using a standardised methodology for surveillance of DRID among PWID, harmonisation of surveillance data among PWID will be useful for comparison, monitoring of progress towards elimination and sharing of experiences and lessons learnt. Ensuring that the sound data that are already available in many situations are reported to the EUDA through FONTE is therefore key to monitoring and reporting on DRID among PWID at European level.

In addition to the reporting of data, there needs to be a plan for dissemination. Who are the key stakeholders to be informed (see also Table 1), to whom and where can the results have impact? Through which communication channel is also important; this will depend on who is on the receiving end; here you can consider electronically through websites, newsletters or social media, but also more scientifically through abstracts and peer-reviewed manuscripts, or through meetings and information days or evenings. Timing of the reporting is also important, to ensure the value of the data as data for action, dissemination should take place as soon as possible after the end of data collection.

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Annexes

Annex 1: Available information and sources on monitoring and survey methodology for PWID

Further reading

ECDC, Hepatitis B – Annual epidemiological report for 2021 (2022).

ECDC, Hepatitis C – Annual epidemiological report for 2021 (2022).

ECDC, Monitoring the responses to hepatitis B and C epidemics in the EU/EEA Member States (2019).

ECDC, Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia – Monitoring implementation of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia – 2022 progress report (2023).

ECDC and EMCDDA, Prevention and control of infectious diseases among people who inject drugs – 2023 update (2023).

EMCDDA, Balancing access to opioid substitution treatment with preventing the diversion of opioid substitution medications in Europe: challenges and implications (2021).

ECDC/WHO Europe, HIV/AIDS surveillance in Europe 2022 (2021 data) (2022).

EMCDDA, Drug-related infectious diseases (DRID) toolkit (2013).

EMCDDA, Monitoring the elimination of viral hepatitis as a public health threat among people who inject drugs in Europe (2019).

EMCDDA, Drug-related infectious diseases in Europe: update from the EMCDDA expert network (2020).

UNAIDS, Global AIDS monitoring (2023).

WHO, Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations (2022).

WHO, Consolidated guidelines on person-centred viral hepatitis strategic information: using data to support country scale-up of hepatitis prevention, diagnosis and treatment services (2024).

WHO, Consolidated strategic information guidelines for viral hepatitis planning and tracking progress towards elimination: guidelines (2019).

WHO, Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework (2016).

WHO, New recommendation on hepatitis C virus testing and treatment for people at ongoing risk of infection – *Policy brief* (2022).