European Monitoring Centre
for Drugs and Drug Addiction

Protocol for the implementation of the EMCDDA key Indicator

Drug Related Infectious Diseases (DRID)

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PROJECT CT.04.P1.337

Note 2012: this protocol has remained draft since 2006 on request of Member States, in order to provide more time for conceptualisation of methods and indicators. In 2009, rather than finalising the current document, the advisory group suggested to change it into a future 'toolkit' with separate modules. Two modules on 'behavioural indicators' and 'example questionnaire' have been prepared in 2011 on the basis of the 2009 and 2010 work. A third module is being prepared during 2012 on 'study methods for sero-behavioural studies'.

In this version of the document earlier comments and notes are maintained that followed from the discussions so far. Additional suggestions regarding recruitment have been kindly provided by Lisa Johnston. The annotated version of the draft protocol here provided should thus be regarded a working document for discussions at the meeting only, and should not be further distributed. The original draft protocol 2006 version is still available (with original questionnaire) at http://www.emcdda.europa.eu/themes/key-indicators/drid
Some general discussion points from previous discussions:

- **Add links with case reporting / notifications based surveillance**
- **Add more guidance on biological sampling options?**
- **Can we give recommended 'best' method instead of many options?**
- **Revise and clarify case definition / target group**
- **Develop form for incidence data?**

An EMCDDA project contracted with the Greek REITOX Focal Point, University Mental Health Research Institute (UMHRI)

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EMCDDA / Greek REITOX Focal Point UMHRI

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With further comments and contributions from the EMCDDA expert group on DRID – most notably the experts participating at the 2004 and 2005 EMCDDA DRID expert meetings see http://www.emcdda.eu.int/?nnodeid=1375

CONTENTS (hyperlinked)

Summary

1. INTRODUCTION

1.1. INFECTIOUS DISEASES MONITORING FOR EPIDEMIOLOGICAL PURPOSES

1.1.1. Epidemiological data for the prevalence of infectious diseases among IDUs

Infectious diseases are among the most serious health consequences of injecting drug use, and have a major impact on the economic and social costs of drug use (EMCDDA 2003). IDUs may also act as 'core groups' or pockets of infection that pose a continuous threat of spread to the general population (EMCDDA, 2000a).

The most recent epidemiological data indicate that the HIV epidemic has recently spread rapidly in some of the new EU countries but has remained around zero in most others, and has mostly stabilised or declined in the 'old' 15 EU Member States. However new rises have been observed in some subgroups of IDUs and local studies, indicating the danger of complacency. The prevalence of HBV and HCV antibodies among IDUs is generally very high (6-85% and 17-95% respectively). Injecting drug use can also be a route of transmission for a range of other infectious diseases like IDU-related tetanus, wound botulism, tuberculosis and STIs (EMCDDA 2004).

1.1.2. The need for a system of infectious diseases data collection

Infectious diseases monitoring systems are an important source of information in the field of drug epidemiology and public health. They can provide valuable information on prevalence rates of drug related infections and their trends over time. This information is necessary for identifying priorities for preventing further infections, for forecasting health-care needs and costs, and for monitoring the impact of preventive interventions. In addition, the data can be useful for indirect estimation of incidence, prevalence and trends in drug injecting.

1.2. THE DEVELOPMENT OF A EUROPEAN STANDARD FOR THE MONITORING OF INFECTIOUS DISEASES

1.2.1. The DRID Indicator

Drug Related Infectious Diseases (hepatitis B/C and HIV), is one of five key epidemiological indicators used by the EMCDDA to determine the prevalence and health consequences of drug use.

The purpose of this key indicator is:

a) to measure levels of infection (prevalence rates = infection rates = % infected) in drug using populations and subgroups
b) to monitor trends over time (increases or decreases in prevalence, infections in new subgroups of IDUs, changes in prevalence among young or new IDUs which may give some indication of changes in incidence in these IDUs),

c) to permit assessment of the effects of control measures, facilitate research, monitor levels of vaccination (HBV, HAV), trends and policies (Okruhlica 2004) and
d) following recommendations made at earlier expert meeting with regard to behavioural surveillance, to collect aggregated data on injecting risk behaviour (current needle sharing) through ST9 from 2006 onwards.

In the European Union, existing data on hepatitis B/C and HIV (studies, routine data) are collected through the REITOX National Focal Points and nominated national experts who meet once a year in an expert meeting in Lisbon. Most data refer to prevalence rates of infection (% infected) with hepatitis B and C and HIV among IDUs. The EMCDDA has developed draft guidelines (EMCDDA 2000a[A1]) and a standard data reporting table (Standard Table 9) for the National Focal Points to collect the data, based on two complementary approaches:

1. collection of existing data from routine sources, i.e. prevalence indicators and notification data;
2. implementing community-wide studies.

In general, the data collected by the EMCDDA are still difficult to compare between countries and are not always of sufficient quality to permit reliable conclusions at country level owing mostly to both scarcity of data and to differences in settings and study methods. Although the availability and quality of data have greatly improved in recent years, and they now permit the drawing of broad conclusions about differences in prevalence between countries and regions, the need for further improvement is evident[A2].

1.2.2. Previous studies and projects

A list of all the reports in English of studies and projects in the field of monitoring infectious diseases and risk behaviours among IDUs that have been critically read and used as a basis for the development of this protocol is presented in Appendix 5[A3].2. For a description of the procedure followed please refer to '*Steps that have been followed'* in Appendix 5.4.

The objective of mapping and comparing the existing protocols and questionnaires was to retain comparability with existing monitoring systems. In addition, a special attempt was made to retain where possible comparability with other well established EMCDDA indicators like the Treatment Demand Indicator which is implemented following the TDI Standard Protocol 2.0 and to take into consideration earlier relevant studies of the Centre (EMCDDA/Trimbos 1999, Okruhlica 2004).

1.3. THE NEED FOR A NEW PROTOCOL

1.3.1. Purpose

Data collection is not an end in itself. The main purpose of tracking an epidemic is to provide the information needed to change its course. Unless the information is used to design prevention programmes focused on those most at risk or most likely to benefit, and to plan for care and support needs brought about by the epidemic, the effort is wasted (UNAIDS/WHO 2000:7).

The general objective of this protocol is to monitor infectious diseases and risk and protective behaviours among drug users with a special focus on ever injectors.

The main objective of this protocol is to improve data quality and comparability from existing routine sources and to set up truly comparable local European seroprevalence studies among IDUs through the development of a multipurpose core item list, plus an additional list of optional items, which is as far as possible compatible with the studies' protocol, standard table 9, treatment screening protocol and main ongoing external studies. Some examples of subsidiary objectives could be assessing infectious diseases in (injecting) users of low-threshold services or other specific settings, assessing the overall public health burden of disease including among past drug users, etc.

It is important to note too that this protocol too is not an end in itself. Data on prevalence of infections and risk behaviours must be combined with estimation of the number of IDUs if proper planning and programming is to be implemented. This objective, however, will not be further discussed here as it falls outside the scope of this Protocol.

1.3.2. Prevalence or incidence?

Prevalence data are more feasible to collect and indeed this is what most countries report and what this Protocol mostly describes.

Monitoring incidence of disease and of injection is of great importance but also difficult to include due to its complexity. Some indirect indicators of incidence could be derived from the implementation of this Protocol, such as prevalence in young and 'new' injectors and prevalence among those with a self-reported or preferably known previous negative test result with known date.

Add some lines on cohort studies, STARHS and notification data

1.4. DATA TRANSFER FROM THE NATIONAL SYSTEMS TO THE DRID INDICATOR VIA STANDARD TABLE 9 (ST9)

(Will be completed after the ST9 is finalised)

Briefly describe ST9 here? (structure, main variables, collection process)

….. mention Fonte, also mention ECDC/WHO, add some lines regarding implementation of Key Indicators somewhere and EU drugs action plan

1.5. ROUTINE DIAGNOSTIC TESTING AND SERO-BEHAVIOURAL SURVEYS

The main principle of the epidemiological surveillance of DRID Indicator is the identification of the extent of health problems by collecting aggregated data on infected individual drug users across Europe (percentage infected and other variables, HIV case reports and hepatitis notifications), with the goal of monitoring and minimising disease transmission. A surveillance system should provide the

means for the ongoing collection of data, their analysis, the dissemination of the results and the implementation of a response based on these results.

Following the results of the previous DRID expert meetings and a recent EMCDDA review (Okruhlica 2004), two approaches to monitoring prevalence and incidence of infectious diseases in drug treatment and other routine settings have been suggested. It is recommended that they be carried out simultaneously as complementary approaches:

- routine surveillance with ***a minimum core set of variables***, easy to collect, for basic epidemiological orientation only, but with high geographical coverage. It is based upon *diagnostic tests* performed in the framework of routine sources (e.g. screening in drug treatment settings). Routine diagnostic testing is limited and its results are potentially strongly biased downwards ('closer to incidence') as known infections are often excluded, although repeat testing of known infections could in theory also introduce an upward bias in the prevalence measured.
- sentinel surveillance with **an *extended list of items***, for more in-depth sero-behavioural studies, with higher information value, but with lower coverage (e.g. in one or preferably several cities and towns).

Need to mention case reporting and notifications here as prevalence is complementary to case-based surveillance. Need to add rationale for the need for both prevalence and case-based surveillance. Could adapt national systems to epidemiological stiatution, e.g. where prevalence is very low perhaps notifications/casereporting suffices, where prevalence starts rising or is high then more intensive behavioural surveillance is needed. Note however that behavioural surveillance may be needed to keep prevalence low!

1.5.1. Serobehavioral surveys

Repeated community-wide surveys represent a very effective approach for collecting data on infectious disease prevalence, including proxy measures for incidence, and for monitoring trends over time.

The added value of such surveys is that they include several indicators for tracking and monitoring key and mostly risky behaviours. Behavioural data are imperative in order to interpret and explain the trends recorded in the prevalence of infections in a population and can be used in planning and evaluating appropriate responses. They can pinpoint behaviours which continue to expose people to infections and interventions can be designed to try to reduce those risk behaviours. Linking behavioural and serological data has higher explanatory power and is common practice in specialized research studies although its higher logistic and ethical complexity has been acknowledged (FHI 2000, Sivaram et al 2005). It is particularly important when the subpopulation under study has adopted highly risky behaviour and contributes disproportionately to the spread of infections; IDUs belong to this category in many countries.

However, it is important to remember that sero-behavioural surveys are not a panacea. For instance, the observation of a decline in prevalence and a parallel change in behaviour may not be enough to attribute direct causal effects[A4].

"Well-designed quantitative surveys can give a very good idea of what behaviours exist, of how common they are, and of whether they are changing over time. However they cannot determine why these behaviours exist, or why they are or are not changing. In depth studies using different anthropological methods are needed to answer the 'why' question[A5]". (FHI 2000:4)

Moreover, a survey is only as good as its sampling design, and this may be a hurdle that is not an easy one to overcome. To provide a representative picture, there would have to be a sampling frame available on which to base the survey. In the other case, where one is not available, sampling might still provide a more controlled system of data gathering, but could not be claimed to provide a 'representative[A6]' picture of the situation as a whole.

1.5.2. Linked vs unlinked data

Many studies utilized unlinked, anonymous methodology under the following conditions:

- The specimens used were collected for reasons other than the HIV testing. Only routinely collected information, unlinked from personal identifiers, was recorded.
- Data were not analysed or reported for small populations if identification of individuals was a possibility
- Studies were only carried out where voluntary testing was available
- The population tested was informed of the research

Public Health Agency of Canada, 2006

Data can be defined as 'linked' when they can be traced back to the individual and as 'unlinked' when they cannot. With regard to infectious diseases monitoring this has multiple ethical implications (see section 2.1.4.3. for details on ethical issues).

For linked or unlinked data there are two main issues that have to be taken seriously into consideration. One is confidentiality of data and how this is best assured. Unlinked data are an excellent solution when researchers want to capture a 'hidden' or 'hard to reach' population whose members would not choose to be identified by official services. This is often the case with subgroups of IDUs who do not wish to have contact with drug specialized or medical services.

The other issue is the validity of the data, which is closely interconnected to the methods used for testing. A test result can only be given to an individual when it is certain and confirmed, which is the case when results are confirmed by the appropriate laboratory testing and confirmatory methods. In this sense results derived from other biological sampling methods that are not 100% reliable should not be given back to the individuals. But in practice, going for the method of testing with the highest possible reliability and providing the individual with the test result, translates into using highly elaborate methods in all phases of the procedure (e.g., trained staff for specimen collection, pre-test and post-test counselling), extra

invested time and ultimately much higher cost. Although this approach is strongly[A7] recommended when resources allow, it is acknowledged that it may not be feasible in a considerable number of countries.

In the context of epidemiological surveys a testing method with high but not 100% sensitivity is sufficient for estimating the current situation of an epidemic in a country, for making projections of the future and for planning resource provision.

Ultimately the choice of whether to go for linked or unlinked data depends on the purpose of testing, the specimens collected, the populations and sites selected and logistics[A8].

1.5.3. Where do routine diagnostic[A9] testing and sero-behavioural surveys meet?

Routine diagnostic testing, performed either in specialized drug treatment and harm reduction services or in other diagnostic settings (like laboratories), and sero-behavioural surveys are not either-or options. They are complementary approaches and ideally countries should opt for both: as the two approaches have different advantages and disadvantages, their combination can yield results of high validity and interest. A brief presentation of the pros and cons of the two approaches is given in Table 1 that follows:

	PROS	CONS
Routine Diagnostic Testing	✓ Wide geographical coverage (national) ✓ Less costly if using existing data systems ✓ Few items: easy to collect	✓ Few items: of more limited use ✓ 'Prevalence' may be very biased, usually lower quality data ✓ Ethical issues, e.g. do patients know that results are used for a study and do they consent
Sero-behavioural surveys	✓ Community wide recruitment, 'more representative' ✓ Longer list of items ✓ Gain detailed information, 'why' and 'how' questions	✓ Expensive, difficult to sustain funding ✓ Often limited geographic coverage ✓ Practical issues: confirmation of results, counselling before and after the results, providing the participant with the results

Routine testing and behavioural surveys may be merged into one and the same approach. A good example of this is the Unlinked Anonymous (UA) Survey of the Prevalence of HIV, HBV and HCV in IDUs, which forms a part of the ongoing national surveillance of these blood-born viruses in the UK (reference). This survey is designed to run throughout the entire calendar year in medical and non-medical settings as well as through street recruitment. The development of saliva and dried blood spots samplers for HIV, HBV and HCV allowed testing to be carried out easily in non-medical settings. The added value of the survey plan is that it simultaneously

records behavioural and demographic information on an anonymous questionnaire. Personal identifiers are removed from the sample before testing, ensuring that both the sample and the questionnaire are anonymous and consequently that the results cannot be traced back to the individual. This is called unlinked anonymous data. It can not however provide individual test results back to the participants who must take a separate test if they wish to know their status. Although such an approach probably produces prevalence data of better quality, separate resources are needed for diagnostic testing, and the approach does not contribute directly to a higher rate of known test results in injecting drug users[A10].

Paragraph on case reporting and notifications

Paragraph on assessing the implementation of DRID

(put excel assessment form in annex) Note to check that the main performance indicators of the assessment form are in some way reflected in this document[A11].

2. METHODOLOGICAL GUIDELINES

Methodological guidelines form the largest and most important part of this protocol. Some of these issues are common to both routine diagnostic testing and sero-behavioural surveys, while others require different handling according to which approach is followed. For this reason it was felt that it was most practical to divide the list of methodological issues into three broad categories: (a) issues common to both approaches, (b) issues specific to routine diagnostic testing and (c) issues specific to sero-behavioural surveys

2.1. COMMON METHODOLOGICAL ISSUES

2.1.1. TARGET GROUP AND CASE DEFINITION

The idea behind defining the target group for surveys and the "cases" that should be included at routine diagnostic testing is that the definition should be as flexible as possible so that it is not too difficult to adapt existing monitoring systems and survey protocols to the DRID Indicator protocol.

At the same time it is acknowledged that subgroups (like current IDUs, ever-IDUs) should be well defined and that questions in the questionnaire should be chosen and phrased in such a way as to allow each country to identify and separate in the analysis the various subgroups and to report to the EMCDDA the data requested at EU level (e.g. Standard Table 9 up until now has been collecting data for ever-IDUs).

2.1.1.1. Target group and inclusion criteria for surveys[A12]

The final suggestion for the inclusion criteria is based on a combination of the definition of problem drug use (PDU) used for the PDU Indicator of the EMCDDA and the inclusion criteria of the EMCDDA/Trimbos (2000) report.

This means that the widest definition in this protocol is the EMCDDA PDU[A13] definition "Injecting drug use or long duration/regular use of opiates, cocaine or amphetamines". Users of the protocol can opt to limit the survey to recent or current PDUs (see definition below) or to ever-IDUs (among the recent or current PDUs), or current injectors, and so on.

It is important to note that if the target group is wider than IDUs, results should be reported for ever-IDUs and never-IDUs separately. Ex-problem drug users who are also never-IDUs should not be included. See Annex 5.10 for a more detailed proposal accepted by the editorial group following the editorial meeting for this protocol.

Recent Problematic Drug Users: those who have injected or regularly used opiates, cocaine, amphetamines in the last 12 months. This does not include those who have ever injected but not in the last 12 months, nor have used any of the above substances in the last 12 months. This definition includes legal opiates such as methadone and buprenorphine, whether prescribed or not. Regular use is not defined but a specific study should be explicit about how it defines this, e.g. '3 times or more per week in the last 6 months'.

Ever-IDUs: those who have injected at least once in their lifetime.

The following hierarchy of options to narrow down the target group in specific surveys is suggested:

a) Ever IDUs who are also recent PDUs (= the data in practice mostly collected by EMCDDA through Standard Table 9)
b) RECENT or CURRENT IDUs, with further categorisation by drug (e.g. current problem heroin users) or injecting status (e.g. current injectors); it is important to be explicit about which users among recent PDUs were actively excluded
c) Recent PDUs (make explicit that ever IDUs who are not recent PDUs are excluded; report ever IDUs among the recent PDUs separately from the never IDUs)
d) Ever IDUs (make explicit that this includes ever IDUs who are not recent PDUs)
e) EMCDDA general PDU definition (make explicit whether or not this includes ever IDUs who are not recent PDUs; report ever IDUs separately from never-IDUs)

2.1.1.2. Which "cases" should be included at routine diagnostic settings

For the purpose of infectious diseases testing and reporting at routine diagnostic settings a **case** is a person/drug user tested for HIV, HCV and HBV during a calendar year from 1 January to 31 December who also meets the inclusion criteria described in section 2.1.1.1. Other infections (STIs, TB, other severe bacterial infections) may be added if countries believe that it is feasible and interesting at national level and may eventually be included in EU level reporting. See EMCDDA testing guidelines at http://www.emcdda.europa.eu/themes/key-indicators/drid

For drug treatment and other specialised drug services

If a person continues a treatment started in a preceding year and is tested during the reporting calendar year he or she is counted in the reporting year. If possible, data on sero-conversion must be reported separately (incidence[A14] data).

For other routine diagnostic settings

As in drug specialised services, it is recommended that all eligible (meeting the inclusion criteria mentioned before) drug users seeking or referred for a test at a service/centre are reported. It is important that these settings can record drug use as risk factor and particularly that injecting drug use (ever, if possible also current) is recorded as risk behaviour among the persons that are tested at these routine general services.

2.1.1.3. Methodological considerations for the case definition

There appear to be two main options for defining the 'cases' for testing and reporting. One option is to include in the reporting system all people being in treatment from the 1st of January to the 31st of December. This is expected to give a very complete indication of prevalence and it is the one strongly recommended. The main disadvantage of it is that the workload for those involved in interviewing, testing clients and in the other steps of the monitoring and reporting system is high.
The second option is including in the monitoring system only people starting treatment in the reference year. This sample is expected to be smaller than in the first option, and if people who report having been positives are not retested we will get an underestimation of prevalence.

In any of the both cases every effort has to be made so that all individuals belonging to the defined group are offered the opportunity to be tested.

It is also strongly recommended that each year's data and test results refer to cases tested in the particular year only. Including results from persons tested at previous year (s) would make comparisons among years meaningless as the very essence of the term 'year' would be neglected[A15].

If a person is tested more than once during the same calendar year, either at the same centre or at different centres, then only the last test in that year is counted. It is, though, recommended that data on sero-conversion can be separated. For example incidence data may be derived from measuring the first occurrence of the infection among those known to be seronegative.

2.1.1.4. 'New' and 'Old' tested cases

A 'new' tested case is defined as a person who is being tested for a particular disease for the first time in his or her lifetime. The distinction between 'new' and 'old' tested cases is important for calculating testing incidence, which is an important indicator for evaluating testing availability at national level. Testing incidence is the number of new tested cases among the total tested cases[A16] in each calendar year. Alternatively, one may find it easier to report the proportion of IDUs in a setting who have taken a test in the last 12 months, this could be seen as 'testing prevalence' and this measure has recently been added by the EMCDDA to ST9.

2.1.2. DATA SOURCES AND RECRUITMENT SETTINGS

The list of sources and settings in the first sheet of Standard Table 9 and the protocol for monitoring infectious diseases in drug treatment and other routine settings (Okruhlica 2004) were reviewed in order to identify relevant settings.

The possible settings for routine diagnostic tests or surveys are:

- Low Threshold Programmes (LTP): It has to be made clear what countries mean by this term as there may be considerable variation. In some countries LTP have a counselling, motivational and harm reduction role; in others they are more therapeutic in the strict sense, prescribing methadone for instance. In general it is thought that low threshold settings may reach a 'more representative' sample of the total IDU/PDU population than clinical settings, although it has to be taken into account that high risk IDUs may be overrepresented.
- Needle and Syringe Programmes (NSP): an important setting as it includes only active drug injectors
- Drug Treatment Centres (DTC): these may include inpatient, outpatient and psychiatric wards or treatment services within mental health care settings (e.g., caring for dual diagnosis patients). The division between substitution and drug-free could also prove useful for some countries. It is always important to combine this setting with open settings such as low threshold, NSP or street recruitment, because drug treatment centres by themselves are thought to have a selected sample of the PDU/IDU population, however this assumption may need to be validated for each country separately.
- Street: this includes the actual streets/scenes and according to certain national situations also venues such as 'drugs flats' (shooting galleries, dealer addresses) etc.
- Public Health Laboratories (PHL): it is unlikely that surveys will include these, but again this may differ among countries e.g. some PHL may provide health services directly to drug users
- Other hospital or clinics, including first aid or emergency wards
- Prisons: this is a very important setting but there may be specific data quality problems, e.g. IDUs in prison may hide their injecting history. This setting needs a special approach and any surveys should be done in collaboration with the European Network on Drugs and Infections Prevention in Prison (ENDIPP).
- General Practitioners (GPs): this can be an important setting but probably only for a limited number of countries. It may also be difficult to use.
- HIV testing centres: important to include if available but known to have a limited coverage among IDUs and to reach especially those with higher risk behaviour
- Overdose deaths: a useful source as it may provide a national sample of IDUs including those who are not in contact with services. However, routine testing of overdose deaths seems to exist in only few countries

2.1.2.1. Open' and 'closed' settings

The above is a quite long list of optional settings that is difficult to work with and may need some simplification. One possibility for simplification might be to divide settings into closed and open settings (e.g. closed: DTC, prisons; open: LTS, NSP, street etc.) and suggest either a ('community wide') survey in open settings or a

combination of open and closed settings, but preferably not only in closed settings as this might[A17] make it more difficult to generalise to the whole IDU population.

The priorities with regard to the above settings may differ significantly between routine diagnostic testing monitoring and sero-behavioural surveys, as well as among countries. The objective for each country should be to reach as 'representative as possible[A18]' a sample of the target population in terms of:

- The geographical distribution of settings
- The geographical distribution of the target population reported to the national treatment monitoring system
- The range of services offered to the target population
- Direct access to the different subgroups of the target population

2.1.2.2. Hepatitis notifications and HIV case reports

Notified or reported cases are an important tool for the surveillance of hepatitis B and C viruses and HIV. It is important to use the DRID Indicator as complementary to these sources of information, particularly to the well-established HIV case reporting systems. Thus it should be evaluated in each country to what extent the DRID indicator is useful, cost-effective and adding value to other established surveillance systems regarding the monitoring, prevention and treatment of DRID in IDUs. Where this added value is high perhaps more investment in the DRID indicator is possible, where other systems seem to fulfil most of the same objectives then the DRID indicator may be implemented less 'heavily' e.g. by reducing the frequency and coverage of studies or monitoring.

It can be important to add HIV prevalence monitoring in IDUs to HIV/AIDS case reporting systems for the following reasons:

1. HIV prevalence monitoring may be less sensitive to miss-classification of IDUs to other at risk groups (e.g. they are less likely to hide their IDU history in a drug service setting)
2. Specific HIV[A19] prevalence testing in IDUs can be more sensitive in low-level epidemics than the reporting of diagnosed cases (especially if including IDUs not in contact with services)
3. HIV prevalence data can be used to validate data from case reporting, e.g. compare trends, compare % on Antiretroviral (ARV) Treatment
4. HIV prevalence monitoring can more easily provide additional variables e.g. behavioural information or uptake of services
5. The availability of extra information, such as 'years since first injection' provides prevalence in new IDUs, as a valuable proxy for incidence.
6. Because it is a relative measure (% infected), there is less need for national coverage, e.g. sentinel studies can provide cost-effective and valid data
7. They are less sensitive to changes in testing policy – numbers tested are accounted for in the denominator
8. They are less sensitive to data protection issues [A20]
9. HIV case reporting is still not implemented in some of the most affected Western-European countries – prevalence data can 'fill the gap'

Notifications for hepatitis B/C among IDUs

Notifications are legally required case reports on the basis of symptoms without a laboratory confirmation and consequently are data without a denominator (number of reported cases or tests). (Wiessing 2005) Notification data on hepatitis can be very unreliable and difficult to compare internationally due to huge underreporting or biased reporting, because a large proportion of asymptomatic cases are not diagnosed as well as because of differences in case definitions. (Hagan et al 2002, Strauss et al 2003, Nalpas et al 1998) However, monitoring the percentage of IDUs among all notified cases may still be relevant as an indicator of the importance of drug injecting as a transmission category. (Harling 2006)

Newly diagnosed cases of HIV among IDUs

Reporting of newly diagnosed cases of HIV has become a cornerstone of HIV/AIDS surveillance in Europe[A21]. It has progressively replaced AIDS surveillance which, since the introduction and widespread use of highly active antiretroviral treatment (HAART) from 1996, has become less meaningful for monitoring the HIV epidemic in Europe. Surveillance data of newly diagnosed HIV infections should be interpreted with caution, because they do not represent HIV incidence data. Furthermore, in the case of recently implemented reporting systems, they may include a large, although declining, proportion of infections diagnosed several years ago. (EuroHIV 2003). Data on newly diagnosed cases of HIV in IDUs are reported by many countries to EuroHIV and consequently provided to the EMCDDA. (Wiessing et al 2000) (Harling 2006)

2.1.3. ORGANIZING THE PRACTICAL WORK

2.1.3.1. Sequence of events

This section will only serve as an example of how best to organize the work since it is acknowledged that there are established procedures for testing and interviewing[A22], at least within each routine setting. A suggested sequence of events is as follows:

- Client contact
- Information on the goals and content of the study
- Written or oral informed consent
- Check the criteria for admittance to the study
- Completion of the questionnaire
- Pre-test counselling
- Test
- Post-test counselling
- Provision of information material on harm reduction
- Acknowledgment of participation and remuneration (where applicable)
- Vaccination (where applicable)
- Referral (if necessary)

Pre- and post-test counselling can be omitted if the test result is not to be reported to the participant. However, informed consent remains necessary even for unlinked anonymous testing and this still is an important opportunity for a very short reminder

of the risks of transmission to the participant. It has become more common practice to reduce or eliminate pre-test counselling, in order to lower the threshold for testing, and to concentrate on post-test counselling which can then be shortened or not depending on the test outcome (to check with expert group[A23]).

2.1.3.2. Record-keeping and ensuring anonymity

A mechanism must be developed so to enable each individual's test results to be entered on the corresponding questionnaire. At the routine setting/centre level it is more usual that data will be stored by name but still, if possible, names and other data or test results should be kept separated. Extreme caution should be taken to ensure anonymity when data are transmitted to the institution responsible for implementing the DRID Indicator.

The agency/fieldworker must keep records of the course of the study and inform the study coordinator of progress made. A mechanism should be designed to record the number of persons who were contacted for the study and of these the number who agreed, refused or were ineligible to participate; the refusal rate is a basic item in reporting a study. Whatever data are available on people who refused to participate should also be recorded because the analysis of the refusal rate in relation to sex, age and other factors may help to support the validity of the study's results or indicate possible biases. It is hoped that individual agencies will achieve a minimum coverage of 50% and a maximum refusal rate of 25% although preferably agencies will strive for better rates. (CDSC 2003) An example of a sheet recording this information can be found in Appendix 5.7

2.1.3.3. Data entry

Once the data have been gathered they must be entered into a computer data file and checked for inconsistencies and errors. This very important step is closely connected to the quality of the final data.

Several types of data check exist and the final choice that each research team makes will depend on time and resources. The most important are recommended below:

- The data are entered twice and the two entered data sets are compared to identify data entry errors. The errors are then corrected.
- The data are checked for inconsistencies, for example non-injectors having replied that they share needles frequently. These must be corrected logically, a possible way being to change the inconsistent values to missing values. Whatever is done must be documented.

Scanning instead of manual data entry can also be chosen. In this case, the interviewers who complete the questionnaires must have been trained in checking as carefully as possible only the appropriate boxes and not writing outside the boxes, and writing, where applicable, as clearly as possible. Clear and well-written questionnaires save time in checking and correcting scanned data that cannot be read by the scanner.

2.1.3.4. Quality control

In discussing the purpose of the DRID Indicator and international comparisons between infectious diseases data, it should be borne in mind that the outcome of this

project and the possibility of making further use of these data depend heavily on the quality of the information collected.

This section provides very brief examples of what may be done to ensure the continual improvement and control of data quality at all phases of data collection, analysis and reporting. Many of the issues presented very briefly below have been also mentioned in other sections of the protocol as they are closely related to other steps of the procedure:

- as many treatment centres and settings and as many setting types ("open" and "closed" settings) as possible should participate in the reporting process and deliver data
- if certain types of settings and centres are under-represented, possible biases should be estimated and reported. It is important to note that if data are available on the total number of centres and their clients, then it will be possible to weight the data in the statistical analysis to allow for under- and over-representation. However this complicates the interpretation of the data and is only sensible if the variable on which the data are over or under-represented is thought to be related to the level of (risk of) infection.
- data collection at the treatment centre and in other routine settings should be complete, thorough, reliable and continuous
- train the relevant professionals in the process of data collection and explain the purpose of this process
- employ the protocol correctly[A24]
- the entire process is piloted before the actual data collection starts
- questionnaires are sufficiently pre-tested and national equivalents for words and phrases that may not be appropriate at the local level are found
- keeping track of questionnaires, i.e. completed, spoiled, returned empty
- a confidential atmosphere is provided for interviewing the eligible participants
- quality checks for inconsistencies and missing values are applied routinely, ideally before and after data entry
- data transfer via Standard Table 9 should be prompt and well organised and also include data validation and data checking procedures
- feedback and exchange of information on all aspects of the monitoring takes place frequently

2.1.3.5. Avoiding double counting

The term 'double counting' refers to a client being registered more than once in an infectious diseases monitoring database in a given year (EMCDDA 2000b). This dual recording may result from the fact that the person collecting the data did not know that the user had already been tested and recorded during the reporting year. A closer look at this issue reveals two basic problems:

- the same client may be tested more than once in a given year in different treatment centres and other routine settings which are not aware of each other; and
- more than one testing may take place in the same centre. This topic has already been touched on in the section dealing with case definitions above. (section 2.1.1.2.)

These two problems are related and have similar consequences. Nevertheless, differences occur when discussing the difficulties they cause and the possible solutions. Double counting leads to overestimation of the total number of persons tested. Counting the same individuals several times during the same year may lead to biased data and may compromise reliable calculations of prevalence and incidence rates.

Assigning unique identifiers to individual clients may help to avoid this problem. Origer (1996) described and analysed the methods used in various countries to avoid double counting in national treatment databases[A25].

2.1.3.6. Data reporting

In principle there can be three levels of data reporting:

(1) treatment centre and other routine setting level;
(2) regional and/or national level
(3) European level and/or international level

Feedback and exchange of experiences and information among all parties involved are of crucial importance. This applies to treatment centres at the local level, the intermediate level of processing institutions and Reitox National Focal Points, as well as the national and international agencies which will make use of the data.

At the local, treatment and other routine setting level, DRID items should become an essential part of the overall data collection process. In many countries, these items, which have been chosen very carefully so that they can also serve national purposes, will form only a small part of the total information collected. In this sense, further processing will be required before data can be provided to the EMCDDA (see section 1.4 for data transfer via ST9).

However, it is essential to pretest and adapt the questionnaire to every local setting in order to identify national equivalents and to define rules for converting regional or national data into DRID Indicator data which is then passed on to the EMCDDA and potentially to other international agencies. This is a very important procedure that further validates and allows a sound interpretation of the relevant information

Caution must be taken that data reported are aggregated and are used for informing the relevant public health authorities and target groups in a non-stigmatising way in order to plan and implement appropriate preventive and service provision responses.

2.1.4. ETHICAL ISSUES

Confidentiality and informed consent are the two broad categories under which all ethical implications can be viewed and are fundamental for any research. When the subject of the research is an illegal or stigmatized activity the importance of protection of privacy is magnified (FHI 2000).

2.1.4.1. Written or oral informed consent

The purpose of the collection of data and the measures that have been taken to ensure confidentiality should be explained to the respondent. Depending on the national requirements, written or oral consent should be given by the respondent,

although it is possible that in some routine settings like treatment centres consent may not be required. An example of informed consent is given in Annex 5.8. If the respondent refuses to participate the interviewer must respect his or her decision and refusal should have no adverse consequences whatsoever.

For the purpose of establishing a mechanism to estimate refusal rates and recording some basic characteristics of non-respondents refer to section 2.3

2.1.4.2. Confidentiality and data protection

Confidentiality and data protection must be assured on all levels:

- The data recorded on paper must be anonymous
- The interview must take place in a quiet place where questions and answers cannot be overheard by others
- If another person enters the room the interview must stop until the third person leaves the room
- Paper questionnaires must be locked in a safe place
- When moving paper questionnaires and serological samples from one place to another, every effort must be made to ensure that these are secured and are not accessible by other people
- Electronic data files, where applicable, must also be locked safely
- Backups should be made and kept in a separate, safe place.

2.1.4.3. Feeding final results back to the respondents

Ideally, individual test results should be fed back to the respondents. But there are two problems in relation to this principle; one is that a result can only be given back when there has been laboratory confirmation. This is not often the case when surveys are conducted. The other implication is that tracing a result back requires that the data be stored by name, which is very often the case at treatment centres and in some routine diagnostic settings but never in surveys.

This is closely related to the issue of linked and unlinked data discussed in section 1.5.2.

This Protocol recommends that if, for some of the reasons already presented, results cannot be given back directly to the individual, then every effort must be taken to ensure that these individuals can be referred to a laboratory centre for a confirmed result, preferably free of charge. In addition, a general back-reporting session should be organised to provide the final study results back to the participants as far as this is feasible, e.g. in the case of a study in a treatment setting or prison.

2.1.4.4. Authorization from national Data Protection Authorities

A research institute or team may have[A26] to obtain official permission for performing a survey from the relevant national data protection authorities.

2.1.4.5. Consulting a Medical Ethical Committee

In countries where a medical ethical committee exists and is active[A27], it is recommended that it should be involved early in the development of the survey plan.

2.1.4.6. Risks of using incentives for participation

The most obvious risks of using incentives for participation in the survey are the reporting of false information in order to appear eligible to participate, and the possible increase in the number of double counts[A28]. The latter can be countered at the quality control of data provided that a unique anonymous code has been assigned to each respondent (see section 2.1.3.5.)

2.1.4.7. Public health issues

When carrying out a survey, particularly when the subject under investigation is engaged in illegal activities, it is important to realise that the survey itself, not just its results, may have serious consequences. One such consequence may be to attract police attention to dealer sites. The research team or the responsible agency must make every possible effort to foresee and avoid any damage to the target group. If there is a real possibility of 'scapegoating' or any other harm to the populations under study it may be better to drop the whole endeavour. As UNAIDS (2003:12) have stated "The desire to know how many people are at risk for HIV should never be allowed to take precedence over the rights and welfare of the members of the populations at risk…"

Another important issue is how to make further use of the results. The results may be negative, indicating for example very high prevalence of infectious diseases among IDUs or positive, indicating low prevalence of infections. Careful handling in accordance with national legislation and health authorities' guidelines is needed so as (a) not to create panic among the public and strengthen social stigmatization towards IDUs, (b) not to give the false impression that drug use or injecting drug use is safe (in the case of low prevalence data), (c) to make sure that data reach the target population and do not remain locked up in some office or are presented only at conferences, and (d) to make sure that they reach all the parties involved and interested in the field so that proper interventions are planned.

2.1.5. INFECTIOUS DISEASES TESTING*

The diagnosis of Human Immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV) infections is generally based on serological testing carried out on blood samples obtained by venous puncture. Nevertheless in epidemiological surveillance, where information is being collected to monitor the epidemic and to plan for needs, tests on specimens that can be collected with minimal training, under difficult field conditions and with minimal risk of infection, will be required. In order to choose the best testing technique for epidemiological surveys one should take into account reliability, feasibility and price. In the case of drug users, the feasibility of using a test depends on the ease of collecting samples and its safety, and the acceptability of the sampling method in these hard-to-reach populations. The need to carry out confirmatory testing or additional laboratory analyses is another aspect to consider in choosing a biological sample to carry out the tests.

2.1.5.1. Biological Samples: Advantages and Disadvantages

- **BLOOD: Total blood serum and plasma.** The blood is collected by venous puncture

Advantages

- Higher concentration of antibody in the blood than other fluids (saliva, urine)
- Possibility of confirmation and additional routine testing (syphilis, hepatitis B, C) with just one sample
- Possibility of special examinations (HIV typing, HIV subtyping, antiretroviral resistance)
- Easy to collect and test in clinical settings with a physician

Disadvantages

- Requires trained and accredited health care workers
- Not easy to collect from injecting drug users
- Requires syringes, collection tubes and needles and consequently safety is required in the process
- Compared to taking saliva samples, venous puncture has higher risk of contamination for health care workers and technicians because of the use of sharp tools and the high concentration of virus in the blood
- Collecting many samples under poor conditions may lead to inadequate preparation and refrigeration, which may cause haemolysis and possible bacterial contamination
- Transporting the samples to the laboratory requires their storage in cold conditions (if transfer exceeds a period of 24 hours after collection).

- **DRIED BLOOD SPOTS (DBS)**

Blood samples from finger are collected in filter paper and tested for detection of antibodies of Hepatitis B, C and HIV. The method is safe and does not require, at least temporarily, cold storage. The sample is transported in a plastic bag.

* This whole section (2.1.5.) is mostly based on the report on biological testing for HIV, Hepatitis B and C infections (Protto et al 2004)

Specificity and sensitivity for HIV testing are 87-99%. For HCV, sensitivity ranges from 95 to 99% and specificity from 99 to 100%. For HBV (HBsAg), both are 99%. Their collection requires training.

Studies indicate that completely dried blood spot specimens may be stored refrigerated (2-8 degrees C), at controlled room temperature (17-23 degrees C) or at elevated temperature for up to three months as long as they are not exposed to elevated humidity.

- **SALIVA**

Saliva sampling is used for population surveys, surveillance programs and personal screening. Specificity and sensitivity for HIV testing are over 99%. For HCV, sensitivity ranges from 85 to 99% and specificity from 99 to 100% and for HBV (anti-HBc) 82% for sensitivity and more than 99% for specificity. The cost is similar to sampling blood.

Advantages

- Easy collection
- It does not require health care workers for the sampling
- No risk of the damage that may be caused by venous puncture
- Can be used in various fields included non-clinical settings
- Greater acceptance by respondents

Disadvantages

- Probably higher cost than the use of plasma or serum
- May require blood sampling for confirmation
- Cannot be used for special studies
- Difficulties exist in obtaining the large volumes of saliva required for good quality

Note: before implementing saliva tests in the study population, the central processing laboratory must validate and improve the replicability of the test. This validation increases the cost of the HBV-HCV testing because serum samples have to be collected to confirm saliva test results.

2.1.5.2. Collection and Storage of Biological Fluids

1. **Venous blood collection**

- Blood must be collected aseptically using a disposable/sterile needle and syringe
- a minimum of 3-5 ml of venous blood must be drawn
- the blood must be collected in a sterile, dry and labelled vial
- the serum must be separated and stored in a refrigerator, if facilities for deep freezing do not exist.

Good record keeping of available stock is important. Stock material should be stored at -20^{o} C or at -40^{o} C in volumes sufficient for the distribution (20 to 50 ml vials). Repeated freezing and thawing must be avoided.

2. **DBS** a) rapid test and b) dried blood spots on filter paper.

Preparation and storage of DBS for HIV test may need 4 hours at room temperature in order to air dry, or 24 hours in humid climates. After they have been prepared appropriately and have been placed in special bags the specimens can be kept for more than 30 days at room temperature and stored at 4° C for up to 90 days. If it is necessary to keep them for longer, they can be stored at -20° C for at least 2 years.

3. **Collection of urine and saliva specimens**

Urine specimens with a preservative may be stored for up to one year at 4-8°C. They must not be frozen.

Saliva specimens can be stored at 4-37°C for a maximum of three weeks (including the time for transfer and testing) and should be refrigerated during transfer. Specimens can be frozen (-20°C) for approximately 3-6 weeks.

2.1.5.3. Transportation of specimens

Specimens to be sent to other laboratories require special attention to safe packaging of the material. Guidelines are usually issued by national authorities and they must be followed strictly. For hand-carried transportation over a short distance, the specimen should be placed upright in an appropriate rack. For long distance transportation, it should be placed in three containers, that is:

- A primary container containing the specimen, which is leak-proof with a screw cap
- A secondary container which is durable, waterproof and made of metal or plastic with a screw cap. It should have enough absorbing material to absorb the contents of the primary container should the latter break or leak. The details of the specimen should be pasted on its outside.
- A tertiary container usually made of wood or cardboard. It should be capable of withstanding the shocks and trauma of transportation. Dry ice can be kept between this and the secondary container along with sufficient absorbents and provision for the escape of carbon dioxide to prevent a pressure build-up inside.

The laboratory must be organized to permit processing of the specimens as soon as they arrive, and the collection of most specimens should be limited to the working hours of the laboratory. However, arrangements must be made to allow for the initial handling of the few specimens that have to be collected outside the laboratory's working hours.

2.1.5.4. Hygiene conditions

During tests it is important to respect principles of hygiene and the protection of the health of workers. Waste generated by the tests which is contaminated by blood must be destroyed in accordance with local legislation in force. Work surfaces or any places smeared with blood must be covered with gauze or paper padding soaked in virucidal disinfectant over the effective exposure period. The staff/fieldworker assisting in the tests must have been vaccinated against hepatitis B (Mravcik V et al 2003).

2.1.5.5. AIDS - HIV TESTING

The diagnosis of HIV infection is based on the detection of antibodies against the virus, usually 3 months after infection (period of searching antibodies 25 days - 6 months) in biological samples.

The detection of antibody is performed usually by Elisa test and the biological samples include blood (total, serum, plasma) saliva and urine. The confirmation is performed by the Western Blot method with blood samples. Specificity and sensitivity of Elisa and Western Blot are 99%.

The techniques of detection separate the tests into two major categories:

A) Standard HIV test: the biological samples of that include blood (total blood, plasma, serum, dried blood spot) saliva and urine.

Advantages

- Large number of samples can be obtained
- Low cost comparing to rapid test
- High sensitivity

Disadvantages

- Requires trained personnel (doctors, technicians)
- Requires a minimum of 2 hours to obtain the results
- Requires special laboratorial equipment and refrigeration of biological samples

B) Rapid test: the biological samples include blood (total blood, plasma, serum, dried blood spots) and saliva. Sensitivity and specificity 84-100%.

Advantages

- Useful for small laboratories with limited infrastructure
- Respondent satisfaction because they receive their results in one visit within 30 minutes.
- Easy and safe use
- Enables autonomy of patients when they select between rapid and standard test

Disadvantages

- Positive and doubtful results should be confirmed. This means taking a blood sample from the patient which will be sent to a specialized laboratory
- Higher cost than the standard test

2.1.5.6. HEPATITIS B TESTING

Hepatitis B virus (HBV) causes acute and chronic hepatitis.

The diagnosis of HBV infection is generally made on the basis of serological markers detected by ELISA assay. Serologic markers of HBV infection vary depending on whether the infection is acute or chronic.

In acute HBV infections, hepatitis B surface antigen (HBsAg) is the first serologic marker to appear in blood. It can be detected as early as 1 or 2 weeks and as late as 11 or 12 weeks after infection by HBV. In persons who recover, HBsAg is no longer detectable in serum after an average period of about 3 months. Hepatitis B antigen (HBeAg) is generally detectable in patients with acute infection; its presence in serum correlates with higher concentrations of HBV and greater infectivity. Antibodies against HBeAg (Anti-HBe) becomes detectable during convalescence, after the disappearance of HBeAg, and remains detectable, generally 1 or 2 years after infection. Acute HBV infection can also be diagnosed on the basis of the detection of IgM class antibody to hepatitis B core antigen (IgM anti-HBc) in serum; IgM anti-HBc is generally detectable at the time of clinical onset and declines to sub-detectable levels within 6 months. IgG anti-HBc persist indefinitely as a marker of past infection. Anti-HBs, antibodies to hepatitis B surface antigen, become detectable during convalescence after the disappearance of HBsAg in patients who do not progress to chronic infection. The presence of anti-HBs following acute infection generally indicates recovery and immunity from re-infection.

In chronic HBV infection, HBsAg is detected in serum for at least 6 months and is associated to the absence of IgM anti-HBc. Both HBsAg and IgG anti-HBc remain persistently detectable, generally for life. HBeAg is variably present in these patients: level of viral activity or replication is assessed by testing for hepatitis Be antigen (HBeAg) and hepatitis B DNA (HBV DNA) in the serum. In most cases, the chronic infection becomes "non-replicative" and the subjects lose serum HBeAg and develop antibodies against HBeAg. In some cases, "replicative" infection persists along with detectable serum HBeAg. In chronically infected individuals, infection can switch from "non-repiicative" to "replicative" and vice-versa.

Biological tests routinely carried out include anti-HBc (blood and saliva), HbsAg (blood and dried blood spots), anti-HBs (blood) and IgM anti-HBc (blood).

Based on a literature review, the sensitivity and specificity of the different biomarkers of HBV are as follows:

- anti-HBc in saliva : 82% for sensitivity and more than 99% for specificity,
  HBsAg in DBS : 99%, both for sensitivity and specificity,
- HBsAg in blood : more than 99 % for both,
- anti-HBc in blood : more than 80% for sensitivity and 90-99% for specificity,
- IgM anti-HBc in blood : 99 % both, and
- anti-HBs in blood : 99 % both.

The costs of HBV tests (only reactive price) are similar to serum. Cost of saliva will be affected by the indirect costs. However, before implementing saliva tests central processing laboratory must validate and improve the replication of the test. The table 1 summarize the different serological markers of hepatitis B in the different phases of infection.
Table 1: *Interpretation of results of hepatitis B testing*

Tests	**Results**	**Interpretation**
HBsAg, anti-HBc, anti-HBs	negative	Susceptible
HBsAg, anti-HBc, anti-HBs	negative positive	Immune due to natural infection
HBsAg, anti-HBc anti-HBs	negative positive	Immune due to hepatitis B vaccination
HBsAg, anti-HBc, IgM anti-HBc anti-HBs	positive negative	Acute infection
HBsAg, anti-HBc IgM anti-HBc, anti-HBs	positive negative	Chronically infected
HBsAg, anti-HBs anti-HBc	negative positive	Possible interpretations: a.recovering from acute HBV infection b.distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum c.susceptible with a false positive anti-HBc d.undetectable level of HBsAg present in the serum; the person is actually a carrier

2.1.5.7. HEPATITIS C TESTING

Testing for the presence of HCV antibodies is recommended for initially identifying persons with hepatitis C virus infection. Testing for HCV antibodies should include use of an antibody-screening assay and, for positive results of this screening test, a more specific additional assay.

Currently, the second-generation enzyme immunoassay (EIA-2.0) for HCV antibodies and HCV Version 3.0 ELISA are the most practical screening tests for detecting HCV infection. For ElAs, reactive specimens are retested in duplicate. If the result of either duplicate test is reactive, the specimen is defined as repeatedly reactive and is interpreted as screening-test--positive. A negative result is interpreted as anti-HCV negative; typically, persons whose anti-HCV test results are negative are considered uninfected.

All of these immunoassays use HCV-encoded recombinant antigens. The sensitivity and specificity of ElAs are higher than 99 and 96%, respectively. The diagnosis of HCV infection can be supported or confirmed by the recombinant immuno-blot assay (RIBA) or tests for HCV RNA.

Currently, the majority of laboratories report a positive result based only on a positive result to screening test, and do not verify these results with more specific serologic assays or nucleic acid testing. To promote the use of additional testing, the Centers for Diseases Control (CDC) have recommended using the signal-to-cut-off ratio of screening test positive result to minimize the number of samples requiring an additional testing and provide result that has a high probability of reflecting the person's true antibody status. A negative RIBA result is interpreted as negative HCV antibodies and indicates a false positive result of the screening test. In this situation persons are considered uninfected. A positive RIBA result is interpreted as anti-HCV positive. Although the presence of anti-HCV does not distinguish between current or past infection, a confirmed anti-HCV positive result indicates the need for counseling and medical evaluation for HCV infection, including additional testing for the presence of virus (nucleicacid test-NAT or HCV RNA) and liver disease (alanine amino-transferase, e.g.). Anti-HCV testing usually does not need to be repeated after the anti-HCV positive result has been confirmed (CDC 2003, www.hepatitis-c.de/diagnosi.htm). An indeterminate RIBA result can occasionally occur among recently infected persons in the process of serologic conversion, and among personschronically infected with HCV. In this case, another sample should be collected for repeat anti-HCV testing (1 month later) or for HCV RNA testing (Figure 1). However, a high proportion of indeterminate RIBA results is usually attributable to false reactions.

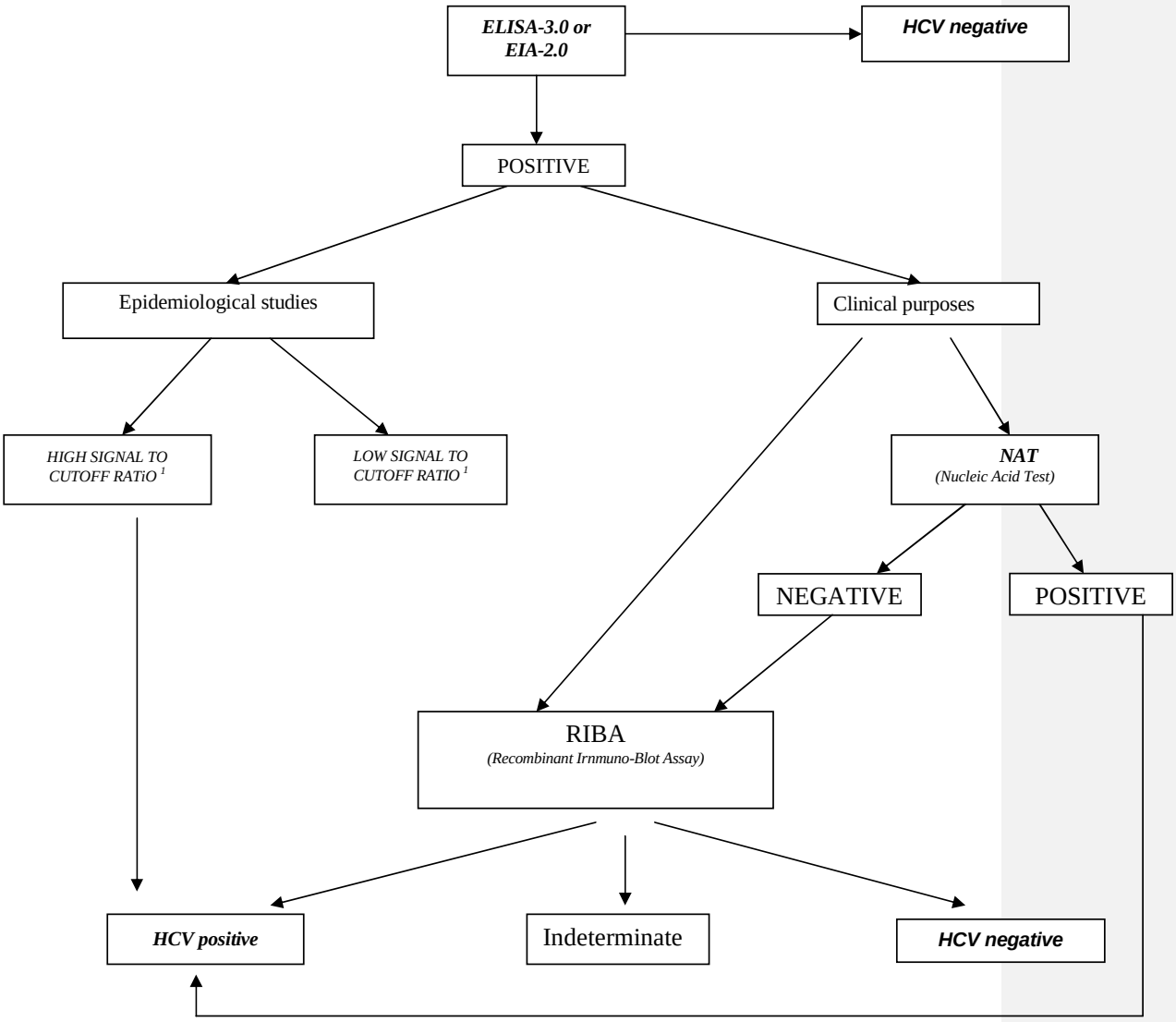
The nucleic acid tests (NAT) are commonly used in clinical practice as additional tests for the diagnosis of acute and chronic HCV infection and for evaluating and managing patients with chronic hepatitis C. The techniques used for HCV RNA detection (CDC 2003) are qualitative reverse transcription-polymerase chain reaction (RT-PCR) and transcription-mediated amplification (TMA).

If the NAT result is positive in persons with a positive result to the screening test, it has the advantage of detecting the presence of an active HCV infection as well as verifying the presence of HCV antibodies (Figure 1). If the NAT result is negative in persons with a positive result to the screening test, the HCV antibodies or infection status cannot be determined. Among persons with these results, additional testing with RIBA is necessary to verify the anti-HCV result and determine the need for counselling and medical evaluation. If the results of the anti-HCV screening test are judged falsely positive (i.e. RIBA-negative), no further evaluation of the person is needed; whereas if the results of the anti-HCV screening test are verified as positive by RIBA, the person should undergo medical evaluation.

Certain situations exist in which the HCV RNA result can be negative in persons with active HCV infection. HCV RNA is not detectable in certain persons during the acute phase of their hepatitis C, but this finding can be transient and chronic infection can develop (CDC 2003, Williams et al 2002). In addition, intermittent HCV RNA positivity has been observed among persons with chronic HCV infection (Alter et al 1992, CDC 2003).

Figure 1: Laboratory algorithm for antibody to hepatitis C virus (anti-HCV) testing and result reported recommended by CDC

[1] Screening-test-positive results are classified as having high signal to cut-off ratios if their ratios are at or above *a* predetermined value that predicts an additional-test-positive result more than 95% of the time among all populations tested; screening-test-positive results are classified as having a low signal to cut-off ratio if their ratios are below this value (CDC 2003)



2.1. METHODOLOGICAL ISSUES FOR ROUTINE DIAGNOSTIC TESTING

2.2.1. RECRUITMENT OF PARTICIPANTS at routine diagnostic testing

2.3.1.2. Contact with 'cases'/clients and interviewing

Each client who attends a recruitment site during the sampling period should be assessed for eligibility (see also section 2.1.1.2. for definition of case). It is recommended that each eligible client should be recorded either by name or by an anonymous identifier, so that the service can calculate the total number of different eligible persons (not the number of attendances) and from these the ones that refused. An example of the sheets for recording this information is found in Appendix 5.7. This information is very important because coverage and refusal rates can be calculated for each agency. The quality of the overall data collected by the survey depends heavily on coverage and refusal rates (see section 2.1.3.2.).

2.2.1.3. Completion of questionnaires

The collection of data from the individual should be based on the completion of a structured questionnaire containing at least all the selected core items presented in 7.1 which the interviewer will record during the interview. The interviewer must ask the questions clearly, unhurriedly and in a factual and neutral manner.

The interview must be held in a quiet place and without others being present. At the end of the interview, some time should be taken to check the questionnaire for completeness and consistency.

2.2.1.3. Training the interviewers in selecting cases and other issues

In a routine setting, the 'interviewer' may be the therapist, a physician, a social worker or a nurse depending on the official procedures for taking a biological sample and recording behavioural data that apply within the agency. Usually the best quality data are obtained if one specially trained person is responsible for collecting data and this is not left to the (busy) clinician. The institution responsible for implementing the DRID Indicator must arrange training sessions so that the definitions of the Protocol can be discussed and any concerns on the part of the staff can be addressed. It may be necessary for a member of the agency's staff (ideally the same person collecting the data) to be appointed as the contact person between the agency and the institution responsible for implementing the DRID indicator.

In addition, a method should be established to ensure that all eligible clients (section 2.1.1.2.) are asked to participate in the monitoring system. Ideally a method should also be established to record the number of eligible clients who attend the setting during the calendar year and of these the number who refused to give sample or to complete the questionnaire (see section 2.1.3.2.).

2.3 METHODOLOGICAL ISSUES FOR SERO-BEHAVIOURAL SURVEYS

2.3.1 PREPARATIONS FOR THE SURVEY

2.3.1.1 Contacting local health and police authorities and services and importance of looking for very early phase joint collaboration

When planning a sero-behavioural survey it is fundamental that a number of key stakeholder groups and individuals agree on the goals of the survey and on the practical issues involved. This procedure may be time-consuming, but on the one hand it ensures that the results will be both usable and used, and on the other it validates the whole process by incorporating ideas and resources from a variety of groups and individuals and it results in 'joint ownership'. Depending on the local or national situation the list of authorities and services that must be involved at the earliest possible stage of the procedure may vary significantly. If there are many, then it may be wise to form a project team with only a few of the most important players but in addition organise a meeting with all those involved in order to obtain broad support.

The objectives of the survey and the expected use of the results must be articulated clearly. They include:

- Which population groups are covered by the survey?
- What does the survey seek to know?
- What information will be collected?
- How will the data and the results be used to benefit the target groups and to help improve national prevention efforts?
- What methods will be used to construct the sampling frame(s) and how big a sample is wanted from the frame(s)

2.3.1.2 Defining and mapping the geographic area and existing knowledge of the 'scene'

The objective of mapping

Drug users and particularly IDUs are considered to be 'hard-to-reach' or 'hidden' populations, because of the illegality of the activity they are involved and the social stigma that is associated with it. Experience has shown that refusal rates are lowest when peer educators and other members of the sub-population at risk are actively involved in mapping, sampling and recruitment... (UNAIDS-WHO 2000:13)

The objective of mapping is to identify sites and locations where sufficient numbers of respondent group members can be found on a regular basis.[1] Through mapping one can identify locations with a large enough number of the target population so that interviewers can return to the same site, randomly select participants and administer behavioral surveillance questionnaires. (UNAIDS ?:4)

Mapping usually leads to revision of the initial sampling plan and is expected to inform the development of an appropriate sampling frame. An estimate of the number of individuals associated with each site is also included in mapping. This is an essential input to the decision on how to allocate the sampling effort. In particular, the probability sampling plans that will be recommended in Section 2.3.2.1. often require that sites should be sampled with probabilities proportional to

[1] From: *Behavioral Surveillance Surveys.* Family Health International, 2000.

the number of members of the target population who can be found there. It is also desirable to establish the pattern of the intensity of use of each site during the day, again in order that the sampling intensity can be decided on in the light of this information.

When trying to identify locations where members of the target group can be found, differences between regions must be taken into consideration. Different cities or regions may have different patterns of drug use and other behaviours that carry a high risk for infectious diseases. Efforts must therefore be made to stratify between areas of high, medium and low prevalence of infections and risk behaviours.

Even when all possible access points, like drug treatment and other specialised drug services, street markets and so on, have been identified and mapped it is important to realise that certain members of the sub-population may be missed. This may be the case, for example, with regard to female injectors, who are often underrepresented because they have limited or indirect contact with the sites and locations that are mapped. Information from the injectors who are accessible can be used to give an idea of the magnitude of the number of those who have been missed.

"It is important that sampling frames cover the entire geographic universe defined for a given survey effort and include the large majority of sites or locations where respondent group members congregate in significant numbers. If not, the resulting survey estimates are prone to bias to the extent that the characteristics and behaviors of target members excluded from the possibility of selection for the survey differ from those who were surveyed" (FHI 2000:34).

In all of these exercises extreme care should be taken so that the rights and welfare of the members of the target group are not violated.

2.3.1.3 Pilot ethnographic observations and estimating target sampling intensity

The role of ethnographic studies in understanding the experience and social contexts of drug use, as well as in informing, questioning and interpreting quantitative research has been illustrated before (EMCDDA 2001, NIDA 1995). Ethnographic methods, particularly participant observation, may identify drug-use behaviours or theoretical constructs previously unexplored which can then be used to "…inform the development of meaningful constructs or measures in quantitative studies…" (Wiebel, 1990 and 1996 as quoted in EMCDDA 2001: 49)

By recording and respecting cultural and sub-cultural peculiarities, ethnographic insights can identify who best to target, with what kinds of message and how best to deliver them. In this sense ethnographic or qualitative research must be considered a prerequisite.

Pilot observations can also contribute significantly to the greater validity of samples. On the one hand, better knowledge of the population allows for greater penetration of the sample into sub-groups that would otherwise have been missed or would be under-represented. On the other, the collection of detailed community-based information helps to reduce the bias resulting from recruiting participants only from already known sources and locations.

2.3.1.4 Informing drug users and services about the study

The services participating in the surveys and the wider community of drug users must be informed about the duration and the aim of the survey.

As far as the services are concerned, this means that all eligible services must be visited before the beginning of the survey at a time when the majority of staff members are present in order to discuss the research protocol and agree on all aspects of the implementation of the survey.

With regard to users not in contact with services, it is important to inform them clearly of the purpose of the study and what is expected from them. This may to some extent be achieved by means of leaflets. It is important that these leaflets should be published in all the appropriate languages appropriate to the country or region, in order to reach drug users of all ethnicities. Some examples of information leaflets from existing survey plans are given in Annex 5.9

2.3.2 RECRUITMENT OF PARTICIPANTS in sero-behavioural surveys

2.3.2.1 Sampling methods

The sampling method specifies how individuals who belong to the population of interest will be selected for inclusion in the sample and hence to contribute data to the survey. There are two types of sampling methods: Probability and non-probability. Probability sampling involves a sampling process whereby every member of the population of interest has a chance of being selected into the sample, with a probability of selection that can be calculated. This type of sampling uses a random method to select participants from a list of population members (the sampling frame). Probability sampling methods are usually representative [A29]of the population from which the sample was gathered.

N*on-probability samples* have been widely used[A30], especially when the survey is aimed at "hidden", "hard-to-reach" or "elusive" populations to which it is difficult to apply traditional sampling methods. IDUs are such a population. Some non-probability sampling methods will be described below. Probability sampling has the major advantage that statistical theory can be applied to the data in order to obtain estimates of the precision of the results. This cannot be done with non-probability samples. Furthermore, non-probability samples are more likely to suffer from bias, because not all population members have an equal chance of inclusion into the sample. Non-probability samples are not useful for comparing survey results between years or places, because differences are more likely to be attributable to the different sampling methodologies (or to changes in the bias associated with the same methodology) rather than to actual differences in the survey resultsIf non-probability samples have to are used – and this should be done only when other methods are impossible or impractical – results should always be interpreted with caution, especially if they are combined at a later stage with information from probability samples. Any efforts to compare sampling methods should be fully documentated.

When selecting a survey sampling method consult existing texts for further information and seek the guidance from an accomplished statistician. Some sampling methods are very complicated and should be conducted in collaboration with someone who has practical experience of the methods.

2.3.2.2 Sample structure[A31]

Most populations are structured in some way that should be taken into consideration in the sample design. One way is *stratification*: if the population is divided into a few well-defined sub-populations (strata), then a sensible sampling strategy is to take a sample from each stratum separately. Many survey designs include geographical stratification (e.g., each city is a stratum). Another example could be a prison survey: each prison is a stratum and provides a sample. Stratification improves the precision of probability sampling (because it guarantees that each section of the population is covered), is often very convenient from the point of view of organizing the survey, and allows us to specify the sample size in each stratum thereby guaranteeing the possibility of presenting separate results for each stratum if this is desired. Stratification often represents the first stage of a multi-stage sample design.
However, when the population is divided into a large number of sub-populations, it will not be feasible to treat them as strata. For example, if the number of treatment units is large, they could not be used as strata. In this case, the groups are called *clusters* instead of strata, and the sampling is carried out in two stages: first, a sample of clusters is drawn; secondly, individuals are sampled only from the selected clusters. There are often overwhelming practical reasons for carrying out clustered sampling – consider the saving in fieldwork cost and time when a sample of size 400 is constructed by drawing 40 clients from each of 10 treatment units compared to drawing 4 clients from each of 100 services. But there is the major drawback that precision is lost. This is because there will usually be a tendency for two individuals from the same cluster to be more alike than two individuals selected at random from the entire population. We lose information because of this *intraclass correlation* – the "effective sample size" is reduced and we need a larger sample than would otherwise have been the case.

2.3.2.3 Sample size

To determine the sample size, it is necessary to decide how accurate the results of the survey must be. For example, if the survey estimate is that 25% of IDU have a certain characteristic, do we want this to be within ±5 percentage points of the true value, or ±2, or what? This is all we need to know in the rare situation that our sample is a simple random sample from the population. In that unlikely case, we could just use the well known facts that (i) the standard error (se) of an estimate *p*% is $p(100-p)/n$, and (ii) an approximate 95% confidence interval for p is found by taking $p \pm 2*se$. So if our desired accuracy is $\pm a$, then we solve $2*se=a$ and find that the necessary n is $4p(100-p)/a^2$. (E.g., p=25, a=5 requires n=300; if we have no idea of what p is likely to be, use 50% to get a conservative answer.) This formula can be improved upon when the sample n represents a considerable fraction of the population N, for in that case the above se should be multiplied by the finite population correction $\sqrt{(1-n/N)}$, leading to a smaller n. Where small absolute numbers are involved, a very approximate system is to note that any estimated *number (not percentage)* has a similar confidence interval of about 2 * square-root of the number (e.g. an estimate of 50 people might lie between +/- 14 on either side of the 50 estimated; or an estimated 9 people */- 6)

But what happens in practice, when we do not have a simple random sample? Usually we have a clustered sample and, as already mentioned, clustering reduces precision (stratification improves it, but expect the clustering effect to dominate). If a similar survey has been conducted before, we are lucky, because from its results we can find the *design effect D*, which can be defined by saying that a clustered sample of size *Dn* has the same precision as a simple random sample of size *n*. Then all we need to do is multiply the *n* obtained from the above calculations by *D.*

If no estimate of the design effect is available, then to assume that *D=2* may be a safe choice (FHI 2000). Reporting the design effect of your survey will be helpful to others who are planning new studies.

When a second wave of a study is being carried out, the required sample size is often calculated on the basis of the desired precision of *changes* between the two waves. The appropriate formula can be found in the report of Family Health International (FHI 2000).

2.3.2.4 Sampling methods for hard-to-reach populations

Hard-to-reach or elusive populations are often sampled using 'adaptive' sampling methods since they do not have sampling frames from which to draw a random sample (Semaan *et al.,* 2002; Magnani *et al.,* 2005). The most widely used methods are mentioned below.

2.3.2.5 Targeted sampling and multi-site sampling

Targeted sampling (Watters & Biernacki, 1989) requires undertaking an ethnographic study of the population in order to understand and map its structure. Using this, possibly in combination with any existing quantitative data on IDUs in the area (from treatment services, police and so on), a sample of locations used by IDUs can be drawn. Researchers are then required to recruit a specific number of respondents, with specific characteristics, at each site. ("Sites" will include streets, parks and so on.)

Any serious survey will be conducted at many sites. However, *multi-site sampling* has sometimes appeared in the literature as if it is a methodology in itself. [A32]The idea appears to be that conducting a survey at enough sites and thereby increasing the heterogeneity of the sample, enhances the possibility of generalizing its results to the total population. This is not true, unless the entire survey has been conducted by probability sampling, including the selection of the sites from a sampling frame of all possible sites. In that case, multi-site sampling is just cluster sampling[A33].

For both of these methods, if the sites in the survey do not include all sites in a given area, then the final sample will be biased and can not be generalizable to the larger population from which the sample was drawn.

2.3.2.6 Snowball sampling

The basic idea of snowball sampling is that sampling begins with a IDUs are selected to provide investigators with the names of other IDUs to contact. Inital IDUs may be sampled randomly or not, however the final sample will not be representative of the

population from which it was drawn. (Hartnoll et al 1997). Recruited IDUs can provide further names of other IDUs, resulting in several stages of recruitment. Snowball sampling is a form of *chain referral* sampling. There are several forms of bias in snowball sampling, including: individuals who know many other IDUs will tend to be over-represented and those who know fewer IDUs will tend to be under-represented[A34]. Snowball sampling has been widely used in the past, but it should cease to play a major role once the study of a phenomenon has moved beyond the initial stages of forming a picture of the problem.[A35]

2.3.2.7 Respondent-driven sampling

Respondent-driven sampling (RDS) (Heckathorn, 1997; Salganik & Heckathorn, 2004) is the latest approach to sampling hidden populations. In essence, it is a chain referral sampling method that incorporates several statistical and theoretical properties which, when conducted and analysed correctly, represents the population from which the sample was gathered. RDS begins with a non-randomly selected group of initial recruits who, with the use of a set number of recruitment 'coupons', recruit their peers. Initial recruits recruit their peers and these peers recruit their peers over the course of numerous successive recruitment waves. Participants receive an incentive for participating in the survey and for recruiting their peers. RDS requires the collection of self reported data on each participant's 'social network size' (total number of peers they know and have seen in a specified period of time). The social network size sets up the probability of selection and is used in place of a typical sampling frame.

The peer recruitment process allows for IDUs to chose whether to participate without coming into contact with investigators and if they do decide to enrol their participation is anonymous and any data collected is managed with a unique number found on their coupon. . Informatin about who recruited whom and each participant's social network size is used to provide adjusted estimates and confidence intervals which permit statistical inference to the total population. RDS data requires specialized analysis using appropriate software. Most RDS data are analysed using RDSAT which is free and available at (www.respondentdrivensampling.org). There is also a widely used manual for RDS preparation and implementation at (ucsf.edu) [A36]RDS has been used widely around the world and there is a wide body of literature on the method. [A37]

2.3.2.8 Time-space sampling[A38]

Time-space sampling is most similar to targeted sampling and, if conducted and analysed correctly,[A39] can be representative of the population form which the sample was drawn. The preliminary stage of ethnographic mapping is used to construct a list of locations used by members of the target population and to obtain information on the density of their use, for example, the number of IDUs attending a location in each 3-hour period of the day. The list of period-place combinations forms a sampling frame for cluster sampling[A40]. Cluster selection should be carried out with probability proportional to size[A41]. Random sampling of individuals is then carried out within the selected clusters, that is, at the selected places in the selected time periods. This random sampling is usually by *systematic sampling,* for example, every *k*th individual attending is selected, where the interval *k* has been chosen to achieve the desired sample size based on the estimated size of the cluster. The success of time-space sampling depends heavily on the quality of the ethnographic

mapping. Note that to be a probability sample of *people* rather than of *attendances at the sampling site,* information has to be obtained on how frequently a respondent attends the chosen site during the chosen time-slot. Time-space sampling can provide probability samples, but its correct implementation is not trivial[A42]

2.3.2.9 Surveys limited to clients in an institutional setting

The easiest and cheapest option available to the designer of a sample is probably to recruit the sample at facilities attended by members of the target population. IDUs can be recruited for a survey at treatment centres, needle exchanges, prisons and other places. A probability sample could be drawn in some of these settings, but it would be representative of that setting, not of the total population of IDU. Clients of institutions almost inevitably are unrepresentative of the total population and therefore the sample will be biased. The size and possibly even the direction of the bias will be unknown. Furthermore, it is not certain that the bias will remain stable over time, so that it is not even possible to compare the results of repeated surveys within institutions, if the intention is to generalize to the entire population.

2.3.2.10 Providing a monetary or non-monetary incentive

Providing an incentive or reward to respondents is often done in surveys of all kinds, but perhaps particularly in those that aim to target hidden or difficult to access subpopulations. The practice has undoubted ethical implications. It is up to the research team, and in accordance with the legal situation within each country, whether or not to include it in the procedure (Pollastri et al 2005). (UK: Boots voucher, Luxembourg: vaccination-consultation)

2.3.2.11 Contact with participants and interviewing

All eligible clients should be asked to participate. A staff member, or a fieldworker in the case of street recruitment, should explain to the potential participant the purpose and goal of the study and what he or she is expected to do. An example of an introductory letter can be found in Appendix 5.6.

Depending on the national practice concerning ethical issues, oral or written consent should be sought. An example of informed consent form is in Appendix 5.8

2.3.2.12 Completion of questionnaires

The introduction is followed by the completion of the questionnaire. Special attention must be paid to ensure that the prospective participant meets the inclusion criteria of the study.

There are different methods of administration of the questionnaire, the most common being interview and self-administered. Computer-assisted administration is less common. Each country is free to choose the method that contributes best to the implementation of the survey, based on its socio-cultural context and the available resources for the survey.

It is recommended to choose interviewer administration, since an interviewer can easily explain unclear points, using social nurses or other professional interviewers in

combination with peer-interviewers with prompt cards for the more sensitive questions.

For injection drug users, it has sometimes been recommended that interviewers be of the same sex as the respondent. However, in situations where access to IDUs involves reaching them in prison, it has been recommended that male members of the team should administer the questionnaire. UNAIDS ?:22. But this may not be the case everywhere. For example in the Netherlands the response rates in surveys outside prisons were not influenced by the gender of the interviewer, while female interviewers in prisons, obtained a higher response rate.

2.3.2.13 Training the interviewers in selecting participants and other fieldwork issues

Training the interviewers is an important part of the survey procedure. To a large extent, the quality of the data they collect is based on the thoroughness of their training. The most important points relevant to the training are listed below:

- Follow tightly the guide with the suggested sequence of events
- Inform people of the purposes of the survey and ask for their informed consent in a neutral way
- Check carefully that the respondent falls within the target group definition
- Ask questions clearly and always record the answers accurately
- When asking a question be neutral and do not indicate your opinions

In addition to the above the interviewers must have received adequate training regarding the correct way of taking a biological sample, the safe storage and transportation of biological samples and completed questionnaires (see also Quality control in section 2.1.3.4.).

2.3.3 DURATION OF SURVEYS

The duration of the study must be clearly defined. It is recommended that the survey runs throughout an entire calendar year or for a shorter designated period of time. A short fieldwork period (a few weeks) has the advantage of reducing problems of double counting and gives a better point prevalence estimate. Different durations are shown in the text below:

- UA: throughout the entire year or for a shorter designated period of time. In the latter at least 100 different eligible clients must be seen during the sampling period
- RIVM: field work period of 3 months
- Luxembourg: a period of 12 months for data collection plus one more year for analyzing and reporting the data
- Czech: 1 year in total, of which 2 months for data collection (including pilot phase)
- Survey among clients at Australian NSPs: 1 particular week in a particular calendar year

2.3.4 SURVEY ANALYSIS

Whenever analysing data, it should be remembered that a description via percentages and means is usually a relatively simple matter, and often provides

useful information in itself. But in order to make quantifiable comments and inferences about the target population that the survey was designed to describe, expert help is required.

The sample design must be taken into account in the statistical analysis, by weighting the data where necessary and by employing appropriate methods of analysis.

The probability of selection for inclusion in the sample does not need to be the same for each individual. If it is, the sample is called self weighting. If it is not, then the unequal selection probabilities have to be taken into account by using weights in the statistical analysis. This makes things a little more complicated, but there is often good reason for having unequal selection probabilities. For example, a survey of IDUs might deliberately over-sample female users: in other words, females would (as a matter of planning, not by chance) represent a larger proportion of the sample than they do of the population. The purpose of this would be to ensure that there were sufficient females in the sample to permit sufficiently precise results to be presented separately for females and males. The importance of this overrides the inconvenience of weighting in the analysis, which is in any case an automatic procedure in most computer programs for statistical analysis.

The method of statistical analysis should not ignore the sample design and simply go ahead as if the data had arisen from a simple random sample. Fortunately, computer software for analyzing data that were obtained through a complex sample design is becoming more widely available. One particular kind of model that has grown in importance in the social sciences in recent years and is appropriate when data have been collected through stratified or clustered designs, or are to be compared between countries, is the class of multilevel models. These make it possible to include not only variables that describe the individuals but also variables that describe the cluster (such as treatment centre characteristics) -within one analysis.

3. CORE AND OPTIONAL[A43] ITEMS AND DEFINITIONS

Questionnaire development is a difficult process particularly when a number of existing national and international studies and instruments have to be taken into account. The process that has been followed in order to decide on the core and optional items is:

- Study other European questionnaires in order to identify the items used and select from them the most common items in all studies (the list was not exhaustive but it is thought that it is representative of the work done within the EU)
- Study other relevant bibliographical references to identify suggested indicators and if possible items used in monitoring injecting drug use behaviour

At the same time every effort has been made to keep the core and optional items as far as possible compatible with Standard Table 9 and the Treatment Demand Indicator (TDI).

Like any other instrument, it is still essential to pretest and adapt it for every local implementation. This involves translating the instrument into local languages and using the appropriate local terminology to ensure that the original meaning of the questions is not lost. It will also be necessary to conduct qualitative research and to involve local members of the target groups who can help with the interpretation of the questions (FHI 2000:69).

All these steps can be better implemented at the pilot phase of the survey which is strongly recommended and ideally should take place some months before the main survey and which will test not only the questionnaire but also the whole procedure.

FHI 2000:70
Among the many items that can help ensure quality, the following check list can be used to improve the instrument:
- Qualitative research before the survey to learn about the characteristics of the sub-populations and how best to approach them;
- Comprehensive adaptation and pre-testing of the questionnaires that are suited to the local context;
- Verification that the language in the questionnaires is clear to the people being interviewed, and that the questions are answerable;
- Taking the time to do translation and back-translation, to make sure that complex concepts are interpretable in a commonly understood manner;

- **Time frames of behaviors or reference periods or recall periods**

One of the most difficult decisions that the parties involved in the development of this Protocol had to take was to suggest preferably one recall period for current or recent behaviour, i.e. the time frame of recorded current or recent behaviour. This is because different relevant studies have been using different recall periods - last 2 weeks, last month, last 3-6 months, last 6 months and last year. Choosing only one of these would either exclude countries that follow a different reference period, or would cause the countries who switched to the DRID Indicator suggestion to lose comparability with data from previous years.

In general it is argued that misreporting of the timing of events is very common and the longer the reference period the more common it becomes (FHI 2003:22). In this sense people tend to remember recent behaviour more accurately and this argues for shorter time frames (FHI 2000:70). On the other hand "…In measuring levels of risk behaviours this misreporting is not very important - the need to maintain standardized indicators over time and between locations takes precedence over the need for a very accurate time reference for events". (FHI 2003:22)

The decision at this stage has been to leave open for a couple of years the choice between the two commonest approaches to recall periods for current or recent behaviour, namely, 1) last month or last 12 months, depending on the expected frequency of the behaviour and 2) last 6 months for all items. A final decision will be taken after the results of different studies have been discussed and compared thoroughly, although at present the first option is the preferred one, given its compatibility with various EMCDDA key indicators (especially the TDI).

3.1. THE RATIONALE FOR CHOOSING CORE ITEMS

From the existing survey protocols and item lists all the items were put into a comparative table (see Appendix 5.3). The minimum common set of items that was also identified as important for studying injecting drug users from the bibliography (Section 4) was chosen.

This process was validated by the process described in annex 5.4.

The objective for choosing core items has been:

a) to ensure their compatibility with the data collected so far through ST9
c) to follow the suggestions from previous EMCDDA projects and othe EMCDDA indicators
c) to keep the core item list as short as possible while at the same time ensuring that it covers the minimum set of key information

3.2. THE RATIONALE FOR CHOOSING OPTIONAL ITEMS

The optional items have been chosen so that countries who choose to include some of them can gather additional information of public health interest, such as risk and protective factors for blood-born diseases, and more complete information on injecting behaviours and service usage. This more extensive information can facilitate the use of detailed behavioural data in planning and evaluating appropriate responses to the infections at national level.

The optional items have been divided to Optional 1 (opt.1) and Optional 2 (opt.2). If the national situation enables the collection of more information than is contained in the core items, it is recommended that a priority is given to optional 1 items and then to optional 2.

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ANNEXES

4.1. FULL LIST OF ITEMS[A44]

FINAL OVERVIEW OF CORE (FOR ST9) AND OPTIONAL ITEMS FOR SURVEYS AND ROUTINE MONITORING

Items in bold are the CORE items and the underlined items are the OPTIONAL 1 items (i.e. the first priority items after the core items). All the rest are OPTIONAL 2 items, i.e. further recommended items and they refer mostly to the case of conducting surveys. v. 09/2006

SECTION A: INTERVIEW INFORMATION

1. **DATE OF INTERVIEW** (in the case the interview is taken separately from the biological sample)
2. INTERVIEWER'S CODE (for surveys)
3. **CODE (TYPE) OF THE SETTING**
4. **CODE OF THE PARTICIPANT**
5. CODE OF THE SURVEY
6. WRITTEN OR ORAL INFORMED CONSENT
7. SAMPLE TAKEN
8. QUESTIONNAIRE COMPLETED

SECTION B: ELIGIBILITY CHECK

1. **Ever injected**
2. **Regular use of opiates, cocaine and/or amphetamines in the last 12 months**
3. **Injected in the last 12 months**
4. **Injected in the last 4 weeks**
5. Interviewed before (for surveys)

SECTION C: SOCIO-DEMOGRAPHIC CHARACTERISTICS

1. **Date of birth OR Age**
2. **Sex**
3. **Country of birth**
4. Nationality
5. Self-reported ethnicity
6. Parents' nationality
7. Current place of residence
8. Duration of living in the current place of residence
9. Current Living status (with whom)
   b. Current living status (where)
10. Duration of living with them
11. Children
12. Highest educational level completed
    b. Age when left school
13. Main source of income in the last 30 days/6 months/ 12 months
14. Religion

SECTION D: DRUG TREATMENT AND NSP

1. **Drug treatment before**
   b. How many times
   c. First time of treatment
   d. Last time of treatment
2. Current drug treatment
   b. **Type of current treatment**
3. Ever used a NSP
4. Current use of a NSP
5. Ever use of a low threshold programme
6. Current of a low threshold programme

SECTION E: DRUG USE HABITS

1. Age of onset of any illicit drug use
   b. Drug of onset of any illicit drug use
   c. Last time of use
2. Age of onset of hard drug use
   b. Drug of onset of hard drug use

c. Last time of use

3. Current drugs used (usual) route(s) of administration and frequency of use
    b. **Current primary drug of abuse**

SECTION F: INJECTING DRUG USE AND SHARING OF INJECTING AND NON-INJECTING EQUIPMENT

1. **Age of first injection of drugs**
    b. Drug of first injection
    c. Inject with a used syringe/needle at that first time
    d. Place of first injection
2. Last time of injection
    b. Inject with a used needle and/or syringe that last time
3. **Current injection**
4. Days of injection
    b. Times of injection on an average day
    c. Times of injection on the last full day

Frequency of SHARING needles /syringes (combined item, not in the questionnaire)
Frequency of SHARING any injecting material (combined item)

5. Frequency of injecting with an already used needle/syringe*
6. Persons taking used syringes/needles from*
7. Serostatus of persons taking used syringes/needles from
8. **Number of persons taking used needles/syringes from** *

Number of persons SHARING used needles/syringes from (combined item)

9. Frequency of injecting with a used spoon or filter*
10. Persons taking used spoon/filter from *
11. Serostatus of persons taking used spoons/filters from
12. Number of persons taking used spoons/filters from*
13. Frequency of injecting with already used water*
14. Persons taking used water from *
15. Serostatus of persons taking used water from
16. Number of persons taking used water from*
17. Frequency of lending used syringe/needle*
18. Persons lending used syringe/needle to
19. Number of persons lending used needles to*
20. Frequency of lending used injecting material other than syringes/needles (spoons, filters, water) *
21. Persons lending used injecting material other that syringe/needle to
22. Number of persons lending used injecting material other than needles to
23. **Number of times reusing your own needles**
24. Froantloading/Backloading/Splitting
25. Ever Injected by others
26. Injected by others in the last 4 weeks
27. Sniffing in the last 4 weeks
28. Frequency of sniffing with a used straw in the last 4 weeks

SECTION G: NEW AND CLEAN NEEDLES AND SYRINGES

1. **Availability of clean/sterile needles/syringes**
2. Places of acquisition of clean and sterile syringes
3. **Number of clean/sterile needles/syringes acquired in the last 4 weeks**
4. **Number of free of charge acquired in the last 4 weeks**
5. Availability of clean/sterile injecting material other than needles/syringes
6. Choices of disposing needles
7. Clean needles/syringes before reusing
8. Frequency of cleaning used needles in the last 4 weeks
9. Way of cleaning used needles

* borrowing (taking) and lending can be merged to the same question by using the word "share".

SECTION H: SEXUAL BEHAVIOUR

1. Sex in the last 6 months
2. Sex with a steady sexual partner
    b. Number of steady sexual partner(s)
    c. Frequency of using condoms with steady partner(s)
    d. Use of condom at last time

3. Injecting status of steady partner (s)
4. Sex with a casual sexual partner
    b. Number of casual sexual partner(s)
    c. Frequency of using condoms with casual partner(s)
    d. Use of condom at last time
5. Injecting status of casual partners
6. "Paid" sex in the last 6 months
    b. Number of "paid' sex partner(s)
7. "Paid" sex in the last 4 weeks
    b. Frequency of using condoms with 'paid' sex partners
    c. Use of condom at last time
8. Serostatus of sexual partners
9. Sexual orientation

SECTION I: PRISON/PENAL(ENDIPP?)

1. Ever arresrted
2. Age of first arrest
3. **Ever in prison**
    b. Times of imprisonment
4. Current imprisonment
    b. Duration of current imprisonment
5. Age of first imprisonment
6. Ever injected in prison
    b. Last time of injection in prison
7. First injection and prison
8. Sharing needles/syringes and other equipment in prison

SECTION J: HIV AND HEPATITIS TESTING

1. Ever having HIV test
    b. **Last time of HIV test**
    c. Result of last test
2. Ever having HCV test
    b. **Last time of HCV test**
    c. Result of last test
3. Ever having HBV test
    b. Last time of HBV test
    c. Result of last test
4. Vaccination against Hepatitis B?
5. Number of doses
6. Time of last dose

SECTION K: HEALTH CARE

1. Diseases you have been told you have and received treatment for
2. Overdosed ever
    b. Times you received professional help
3. Times of recent overdose
4. Blood transfusion ever
    b. Time of first blood transfusion
    c. Time of last blood transfusion
5. Tatooing ever
6. Perceived health status

SECTION L: KNOWLEDGE/ATTITUDES

1. Types of Hepatitis
2. Perceived transmission routes of infection with hepatitis and HIV/AIDS
3. Perceived easiness of treating hepatitis and HIV/AIDS
4. Places of getting informed about hepatitis and HIV/AIDS
5. Preventive measures taken

SECTION M: HOMELESSNESS

1. Homeless ever
    b. Age of being homeless for the first time
2. **Recent homelessness**
3. Duration of recent homelessness

SECTION N: MOBILITY

1. Ever got drugs, injected drugs and borrowed used needles/syringes
2. Recently got drugs, injected drugs and borrowed used needles/syringes
3. Cities/countries you recently got drugs, injected drugs and borrowed used needles/syringes

SECTION O: TEST RESULTS

HBV (specified biological markers)
HCV (specified biological markers)
HIV
Other diseases
Date of serological sampling (if different from date of interview nor recommended)

EXAMPLE QUESTIONNAIRE

See separate document with updated version provided at 2010 DRID expert meeting "4_EMCDDA_Questionnaire_2010_DRID_meeting_27092010.doc"

4.2. LIST OF RELEVANT PROJECTS AND REPORTS[A45]

	Protocols	Questionnaires	Background information
1. Protocol for Screening and Monitoring Prevalence and Incidence of Infectious Diseases in Drug Treatment and other Routine Settings, Lubomir Okruhlica	√	√	
2. WHO – ASSIST V3.0 Questionnaire		√	
3. Luxembourg Protocol and Questionnaire	√	√	
4. Hungarian Epidemiological Questionnaire for the voluntary, anonym screening of the drug users for HIV/AIDS, hepatitis B and C infection		√	
5. Seroprevalence-seroincidence Czech and Austria	√	√	
6. Feasiblility study ….(emcdda-trimbos)	√	√	
7. RAPID HIV TESTS- WHO			√
8. Estimating the size of populations at risk for HIV, Issues and Methods UNAIDS/WHO			√
9. Sampling Younger IDUs, publication			√
10. Finish protocol		√	√
11. IRQ Injecting Risk Questionnaire		√	
12. WHO STUDY PHASE II	Eligibility criteria	√	
13. HCV Infection –Scottish questionnaire		√	
14. 1997 and 2001 prison studies for HIV	√	√	
15. Biological testing Belgium			√
16. Dutch Survey	√	√	
17. Epidemiological survey	√	√	

on heroin use in Belgium			
18. Australian monitoring system	√		
19. The Rapid Assessment and Response Guide (RAR) (WHO-SAB)			√
20. Designing HIV/AIDS intervention studies			√
21. Behavioral surveillance surveys: guidelines for repeated behavioral surveys in populations at risk of HIV *2000 Family Health International*			√
22. Monitoring and evaluating Toolkit			√
23. Belgium-Greece-Slovenia (HC)	√	√	
24. PAHO (Spanish)			
25. Unlinked Anonymous	√	√	
26. The Injecting Drug User Saliva Survey		√	
27. Swiss questionnaire		√	
28. FR Protocols (French)			
29. Comparison of low-threshold material			√
30. Low threshold material 1 (before the meeting)			√
31. Low threshold material 2 (after the meeting)			√
32. Paper on ethical issues			√
33. Paper on analysis on data on risk behaviour that is in the national reports			√
34. Hope AIDS 2005			√

4.3. A COMPARABLE VIEW OF THE ITEMS USED BY SELECTED DIFFERENT REPORTS[A46]

	EMCDDA/TRIMBOS(6)	**WHO (12)**	**Seroprevalence- Czech and Austria (5)**	**Seroincidence Czech and Austria(5)**	**SCOTTISH (13)**	**DUTCH (16)**	**Belgium-Greece-Slovenia (HC) (23) CORE**
SOCIO-DEMOGRAPHIC	**Date of birth** **Gender** **Country of birth** **City of birth** **Ethnicity** **Nationality** **Living situation (with whom)** **Children** **Education** **Source of income** Health insurance **Children** Age of leaving parents	**Country of birth –duration** **Living situation (with whom)** Marital status **Living situation (where)** **Education** Other training **Source of income** SOCIAL CLASS	**Year of birth** **Sex** **Nationality** **Ethnicity** **Education** Area of living	**Education** **Change of education** **Change of residence**	**Partner-User** **Living conditions** **Children (natural, adopted)**	Sex Date of birth City of residence(last 6 months) and duration Country of birth Place of birth Parents' country of birth **Education**	Age, country of birth, place of residence, nationality, parents' nationality, living status, main source of income, education Health insurance
DRUG USE HABITS					Illicit drugs used (**age at first illicit use-overall)** Drug first used	Drugs used, age at first illicit use	Types of drugs, route of administration, frequency in the last 6 months, age of first try, age of onset of regular use, last time of use, frequency of sniffing
Injecting	**First injection** Initiation (age, motives, circunstances) **Last injection**	First injection • Drug, (same drug without injection, frequency duration) • Who with? What **Use in last 6 mos** **Frequency.**	Time of onset Type of drug Timelang of injection Frequency of current injection	Last injection **past 3-6 months** Frequency Primary injection drug Pattern of	**First injection** Occasion **Last injection.** **Last 6 mos;** Still injecting. All illicit drugs. Injection. Frequency	All illicit drugs. Injection. Primary drug injected last 6 mos	Type of drugs injecting now Type pf drug injecting before current treatment Age of onset Time of last

		Specify drug Ex-injectors: frequency, drug, family, last occasion	Usual pattern of injection Last time of injection Injecting abroad	injection abroad			injection Frequency of injection in the last 6 months
Sharing	Sharing (last time + Frequency) Lending (last time+ Frequency) Borrowing(last time + Frequency)	**Sharing last 6 mon : frequency, who with?** Reasons Last 6 mon: lending meedles, equipment (details) Last 6 mon. Borrowing needles, equipment (details)	Ever sharing needles/syringes and first time Sharing of other equipment and onset Sharing injecting equipment with HCV positive Sharing injecting equipment with foreigners	**past 3-6 months** Needle/syringe Kit (filters,spoon, water) Anything with HCV positive Anything with a foreigner	Sharing last (6 mon., frequency, who with) Lending (last 6 mon who to? Borrowing equipment (last 6 mos)	**Sharing last 6 mon (needles, equipment** Lending: last 6 mon Borrow: last 6 mon. Who from, HIV+, reasons	Last time sharing needle Category of people sharing equipment with Frequency of sharing sniffing equipment
Other	**Effective cleaning of equipment** Plans for starting injection Plans for stopping injection Price	**Perceived availability of new needles** Cleaning			**Perceived availability of new needles** Keeping/disposing of needles	Disposing of used needles	Usual practices of cleaning equipment
SEXUAL BEHAVIOUR/RISKS	Steady partner (Use of condoms, fflV status, injecting, prostitution)	Steady partner. Last 6 mon. Frequency. Number	Number of partners ever Number of injecting		Steady partner (Use of condoms, injecting) Casual partner (s)	Steady partner. Last 6 mon. Condoms frequency. User/Injector	Injecting status of partners **Last 6 months**

	Casual partner (condom) **Homosexual relationships (condoms) Prostitution**	Injectors. HIV+, Hep+ **Casual partners. Last 6 mos. Condoms**. Number **Prostitution** (also in DRUG ROLES MODULE)	partners Condom ever "Selling" intercourse Sexual preferences Intercourse with HCV positive		(condoms, injecting) **Prostitution**	Casual partners. Condoms frequency **Prostitution (details)**	Sexual relationships with -Steady -Casual -Same gender Frequency of condom use
INFECTIOUS DISEASES			Ever infected Type of disease			Hepatitis A,B,C-disease-ever	Ever infected Type of disease
HCV	**LastHCV Test**/self-reported results. Treatment	HCV. Ever tested/self-reported results	Ever tested, last test, result		**LastHCV Test**/self-reported results		Time of last test and result
HBV	**LastHBV Test**/self-reported results. **Vaccine**	**Hep.B vaccine**	Ever tested, last test, result Time of vaccination and doses		**Last**HB.V. Test/self-reported results. **Vaccine**	**Hep.B vaccine**	Time of last test and result Ever vaccination
HIV	**Last H1V Test**/self-reported results. **Treatment**	**Last HIV Test/**self-reported results. Counselling. Treatment AIDS disease	Ever tested, last test, result		**Last HIV Test**/self-reported results	**Last HIV Test**/self-reported results	Time of last test and result
Other	Other STDs	AIDS, Hep. knowledge + attitudes				Other STDs	Ever received medical treatment STD treated in the last month
PRISON-PENAL INFORMATION	**No of imprisonments**	**Ever in prison** No of	Ever in prison Ever injecting		**Ever in prison since** initiation of	Frequency of imprisonment	Times The longest one

			there				Started injection in Ever injected in Sharing equipment in
TREATMENT				**Since joining the study** Starting and ending abstinence-oriented outpatient treatment Starting and ending abstinence-oriented inpatient treatment Client of a contact centre Frequency of visits in the last 3-6 months Exchange program Frequency of exchange in the last 3-6 months Etc. Evaluation of the service (for the "yes" and the no"			Current treatment Number of previous treatments Waiting list Needle exchange programme Low threshold Other drug-related services

KNOWLEDGE OF INFECTIONS/ATTITUDES		AIDS, Hep. knowledge + attitudes AIDS Preventive measures taken Use of injection rooms, shooting galleries, etc.	**HCV** HCV among IDUs in the country Risk perceptions Treatment Modes of transmission relation with HBV,HAV Places for counseling, testing, treatment		Knowledge questions for infectious diseases Preventive measures taken Attitudes towards sharing		**HCV/HBV/HIV** Modes of transmission Places you have been informed about the diseases Preventive measures taken
HEALTH CARE							**Last month** -Visit a MD -visit an emergency room -hospitalised
MOBILITY						√	
OTHER:							
Tattoo			√ plus origin of it				
Expression of needs for services							
Attending needle exchange program							
Received blood tranfusion			√				
Hemofilic			√				
Modul multiplicator			√				
Modul of syringe availability and attitudes towards utilization of resources of syringes			√				
Module for never injectors		√					
Module for injection initiation		√					

Module on last injection event		√					
Module on drug roles		√					
Module on violence		√					

4.4. THE STEPS THAT HAVE BEEN FOLLOWED

The following parties contributed to the development of the present Protocol:

- The EMCDDA
- The Greek REITOX Focal Point
- The editorial group of 6 European experts
- The Greek group of 4 experts
- The DRID Indicator expert group

The EMMCDDA made a call for tender for the project and it was awarded to the Greek Focal Point (GFP). The project foresaw a working period of almost 14 months, starting in October 2004.

All the relevant written material (see Appendix 5.2) were listed and critically read. Special emphasis was given to existing national and international protocols and questionnaires, which formed the basis of this work so that comparability with previous studies would not be lost. For this reason two sets of comparative Tables were created, one for a comparative view of all the areas of interest and items used by the existing questionnaires and one for the basic themes included in the existing protocols.

Initially the idea was to develop two protocols with their respective item lists, one for routine monitoring and one for the surveys. This idea was reconsidered as the project progressed and it was decided that one protocol with one item list should be developed for both complementary approaches. This was viewed as a more practical and effective way to deal with guidelines about monitoring.

The EMCDDA in collaboration with the Greek Focal Point (GFP) held a meeting in Lisbon in June with the editorial group of the project which comprised experts from six countries (Czech Republic, Spain, The Netherlands, Slovakia, United Kingdom and Switzerland). The GFP presented the comparative tables and the other draft material (draft outlines, draft item list with suggested core and optional items) that had been prepared up to that time. The experts critically discussed the First Draft survey item list and other methodological issues of the protocol.

Following that meeting, the First Draft Survey Item list was updated and some items were chosen as core, i.e the minimum requirements for data to be collected, analysed and reported. A further decision was made on selecting a limited number of these core items for the routine monitoring which hereafter will be called monitoring of routine diagnostic testing. A meeting with the small group of Greek experts working on this project took place in mid-September where the experts commented on the material developed so far. The Draft Protocol was then prepared.

The Draft Protocol and Item List were sent to the group of experts before the EMCDDA 2005 DRID Indicator Expert meeting which was held in Lisbon in October. The GFP presented the main points of the project, which were discussed further in the meeting. The final phase of this wide exchange of information was completed after this meeting, with the incorporation of the experts' detailed comments on the Protocol and the Item List.

4.5. PRISON MODULE (TO BE FURTHER DISCUSSED)

4.6. EXAMPLE OF INTRODUCTORY LETTER (UA/UK)

HELP US TO HELP YOU BY JOINING THIS SURVEY . . . .

ANONYMOUS NATIONAL SURVEY OF HIV AND HEPATITIS IN DRUG INJECTORS

We are trying to find out how many people who inject drugs have blood-borne infections such as HIV and the hepatitis B and C viruses. If we know this, we can help to provide services to drug users that better suit their needs

All we would like you to do is:

- give a saliva (spit) sample using the device provided
- fill in a short questionnaire

Instructions for giving the saliva sample can be found on the other side of this sheet. The questions are on the coloured paper.

Your saliva (spit) will be tested for the proteins, called antibodies, which the body makes when a person is exposed to viruses. These antibodies can be found in saliva, but only the hepatitis B virus can be spread by saliva.

Your name is <u>not</u> being recorded in this survey. This means that neither you, nor anyone else, can find out your answers or saliva test results.

Participation in this survey is voluntary. Whether you decide to join the survey or not, the services you receive will be the same[2].

If you want to know if you have HIV, or hepatitis, speak to the worker who can help arrange a blood test with counselling.
Please keep this sheet for your information, if you would like to do so.

[2] This sentence omitted for Community Recruitment

4.7. EXAMPLE OF WORKLOAD COLLECTION AND FIELDWORK MONITORING FORM (UA/UK)

WORKLOAD COLLECTION FORM

Name of staff member _____

Client Name or Identifier (✎)	**Agreed to Participate** (✓)	**Refused to Participate** (✓)	**Tested Elsewhere This Year** (✓)	**Voucher Given to Client** (✓)

Note: If client is not asked to participate, only complete the first column. Clients can only participate once in a calendar year - if they have already done the survey, for example at another centre, indicate this in the column titled 'Tested Elsewhere This Year'.

FIELDWORK MONITORING FORM

Name of Interviewer _____

Contact Number (✎)	**Agreed to Participate (✓)**	**Refused to Participate (✓)**	**Tested Elsewhere This Year (✓)**	**Acknowledgement Given to Client (✓)**

Note: Contacts can only participate once in a calendar year - if they have already done the survey, for example at another centre, indicate this in the column titled 'Tested Elsewhere This Year'.

MONTHLY WORKLOAD REPORTING

SHEET - 2004

Centre

Please use the **workload collection form** provided to calculate these figures.

All clients on the list from the *beginning* of the survey in 2004
up to the end of 'month' should be included.

1. How many clients who **have ever injected** have been seen by your agency since **you started the survey this year**? ✎_____

2. Out of all your agency's clients **who have ever injected** and **have been**
seen since the start of the survey in 2004

a. How many **have taken part** in the survey ✎_____

b. How many **have refused** to participate? ✎_____

c. How many **have already been tested** elsewhere in 2004? ✎_____

3. How many survey packs **have been posted** to the Health Protection Agency since **you started the survey this year**? ✎_____

4.8. EXAMPLE OF INFORMED CONSENT

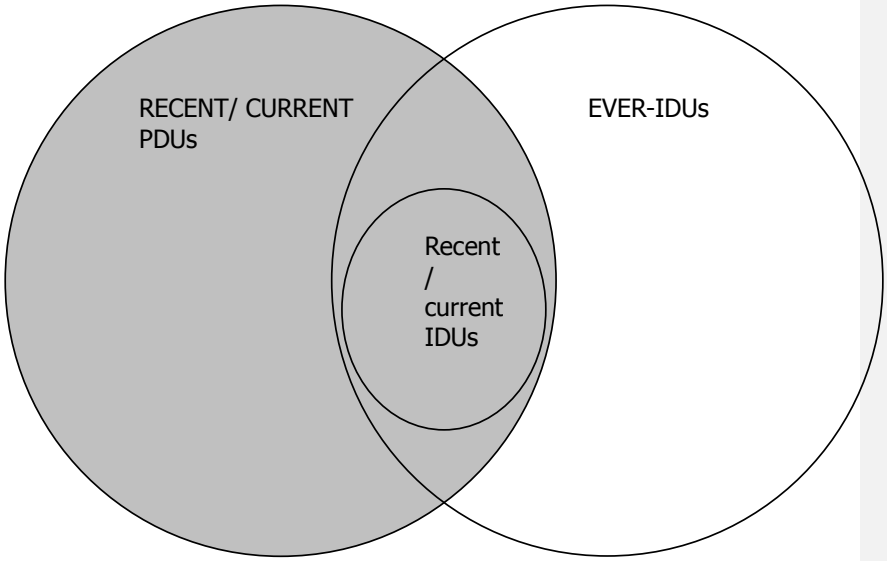
4.9. Other examples of forms

4.10. Target group and inclusion criteria

Target groups and EMCDDA PDU definition, agreed upon by the group following the meeting.

After the meeting a diagram for the target group was proposed by email as follows (relative sizes and size of overlaps of the circles bear no relation to relative prevalences in reality)

Fig. 1 EMCDDA definition of PDU, suggested main target group for inclusion in surveys shown in grey



Notes:

- The current EMCDDA definition of PDU includes 'active' problem drug users, but also does not explicitly exclude people who are not current users of drugs but have ever injected in their life time.

- In practice estimates of PDU relate to a one-year period prevalence (12 months) of people in contact with services. An age restriction is also used of ages 15-64. Depending on the services the estimates mostly relate to recent users (injectors) of heroin, cocaine or amphetamines, but in some cases (e.g. HIV/HCV testing) non-recent users of drugs can be included.

- This is relatively unclear at present and should be distinguished better, i.e. ever IDUs who are not recent IDUs (last 12 months) and are not recent users of the listed drugs should maybe in the future not be included in prevalence estimates of PDU. If they are included in prevalence estimates of (ever) IDU then this should be made explicit e.g. by stating 'including past PDUs who have ever injected'.

- From the above it follows that surveys which aim to sample 'active problem drug users' should have inclusion criteria that measure 'current (in last month or 6 months) or recent (in last 6 months or 12 months) use of heroin (and other opiates), cocaine and/or amphetamines OR current or recent injecting'.

- Given that standard table 9 collects data on 'ever IDUs' it is proposed that the protocol allows a wide target group definition (=EMCDDA PDU definition) but that it would suggest a hierarchy of options to narrow down the target group in specific surveys, for example as follows:
    a) EMCDDA general PDU definition (make explicit if this includes ever IDUs who are not recent PDUs, report ever IDUs separately from never-IDUs)
    b) Ever IDUs (make explicit that this includes ever IDUs who are not recent PDUs)
    c) Recent PDUs (make explicit that ever IDUs who are not recent PDUs are excluded, report ever IDUs among the recent PDUs separately from the never IDUs)
    d) Ever IDUs who are also recent PDUs (= the data in practice mostly collected by EMCDDA through ST9)
    e) further sub-selections by drug (e.g. current problem heroin users) or injecting status (e.g. current injectors) but important to be explicit about what users among recent PDUs were actively excluded.

- To facilitate understanding the words 'current' or 'recent' could be replaced by the respective recall period used (once a decision has been taken) e.g. 'last month injectors', 'last 6 months injectors', 'last year injectors', 'last year problem drug users' etc. It is important to keep in mind the difference between a 'one year period prevalence of current contact with services' (as in prevalence estimates of PDU), and 'point prevalence of last year contact with services' (as from survey data if recruitment period is short).