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Executive
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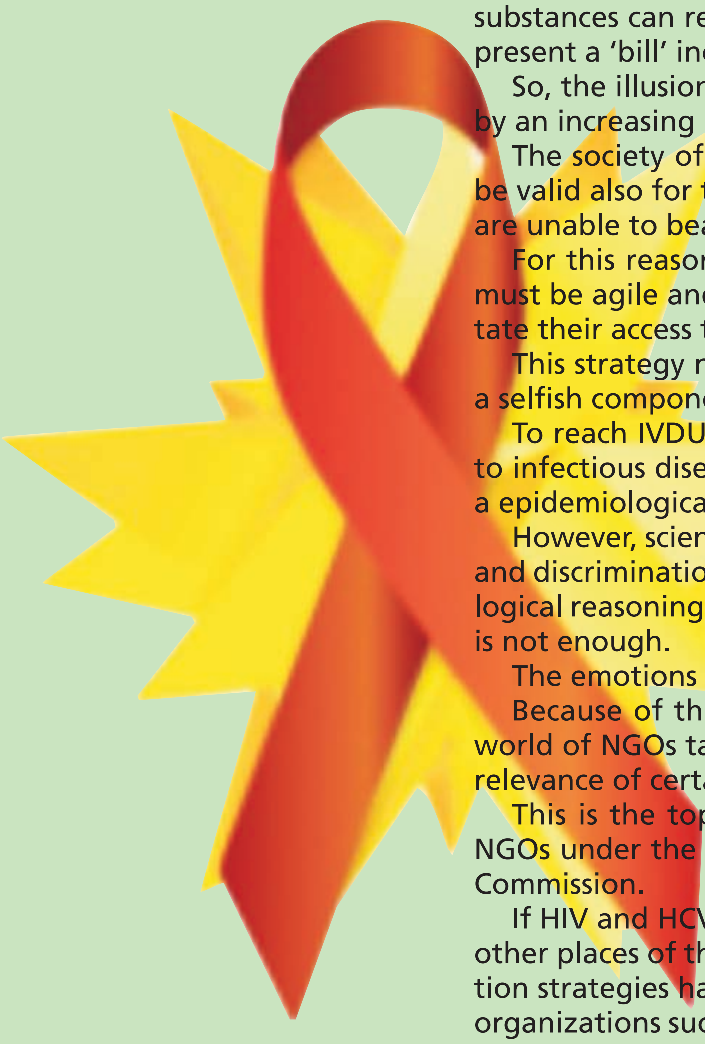
Fondazione Villa Maraini O.N.L.U.S.
GruppoAbele
SANANIM
ODYSSEUS
De Regenboog Groep

Imp.Ac.T.
Improving Access to HIV/TB testing
for marginalized groups

Guide Manual on HIV and TB Testing for DUs and migrants in low-threshold services

Project Imp.Ac.T.
Improving Access to HIV/TB Testing
for marginalized groups

Preface



The difficulties of living affect everyone. However, for somebody life is so complicated to become unbearable. For these people, the use of substances can represent a solution to survive, a cure that step by step present a 'bill' increasingly high.

So, the illusion of integration becomes marginalization accentuated by an increasing isolation.

The society of integrated people cannot believe that its rules could be valid also for those individuals who live on the fringe of society and are unable to bear the frustrations accepted by the majority.

For this reason, health services targeting marginalized populations must be agile and meet the need of most vulnerable, in order to facilitate their access to services.

This strategy not only obeys an humanitarian principle, but has also a selfish component.

To reach IVDU means to prevent also risk behaviours that can bring to infectious diseases easily transmittable to the general population in a epidemiological open system.

However, scientific evidences sometimes are not sufficient: the stigma and discrimination toward some individuals are so high that exceed any logical reasoning, even those frankly utilitarian. In front of stigma, logic is not enough.

The emotions and malice of "Normals" prevail over the logic.

Because of this, it's important that the activists who make up the world of NGOs take the initiative to show to 'normals' the validity and relevance of certain theoretical assumptions.

This is the topic of the present document, jointly developed by 5 NGOs under the protective and challenging umbrella of the European Commission.

If HIV and HCV infections among IVDU fell down in our country and other places of the world where intelligent and aggressive harm reduction strategies have been implemented, the merit is also of civil society organizations such as the ones involved in the project IMPACT. Working together, besides the collection of a consistent quantity of data useful to the scientific community, these 5 organizations have produced a "European added value", result of exchanges and interrelations among workers of the involved services, thus contributing to increase the awareness of all belong to the same country: that of human race.

Massimo

Dr. Massimo Barra
Villa Maraini Founder

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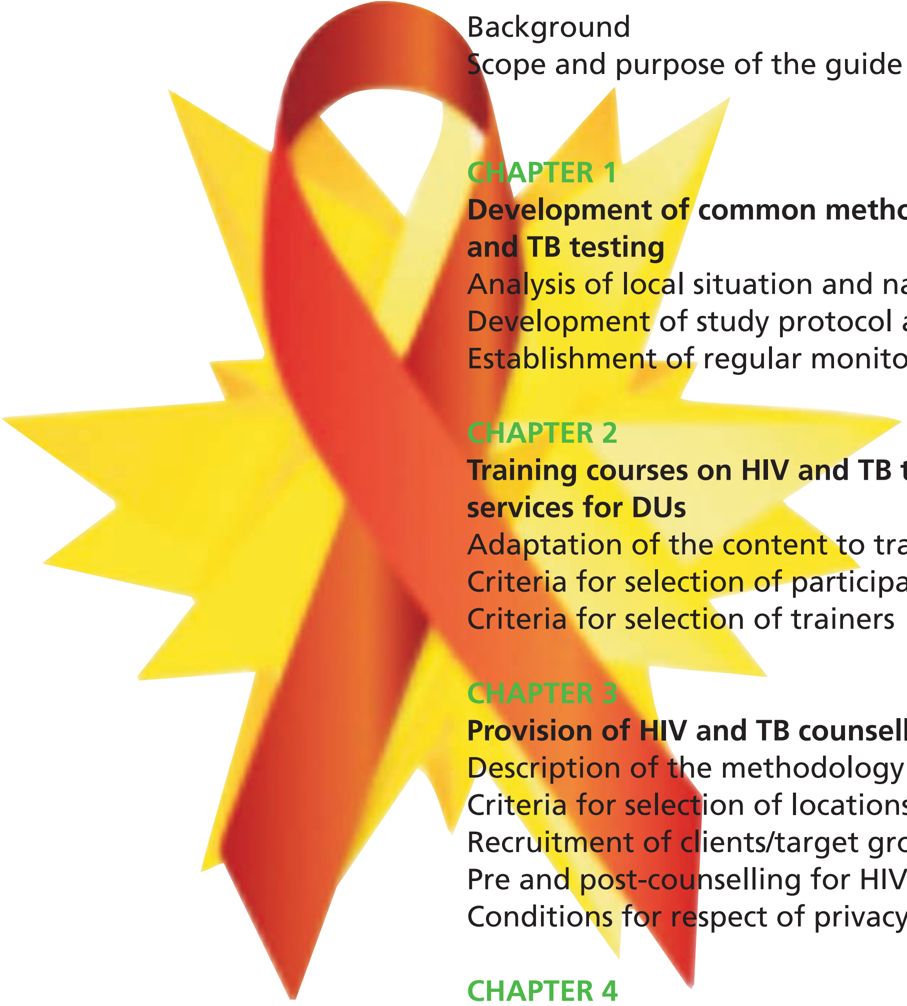

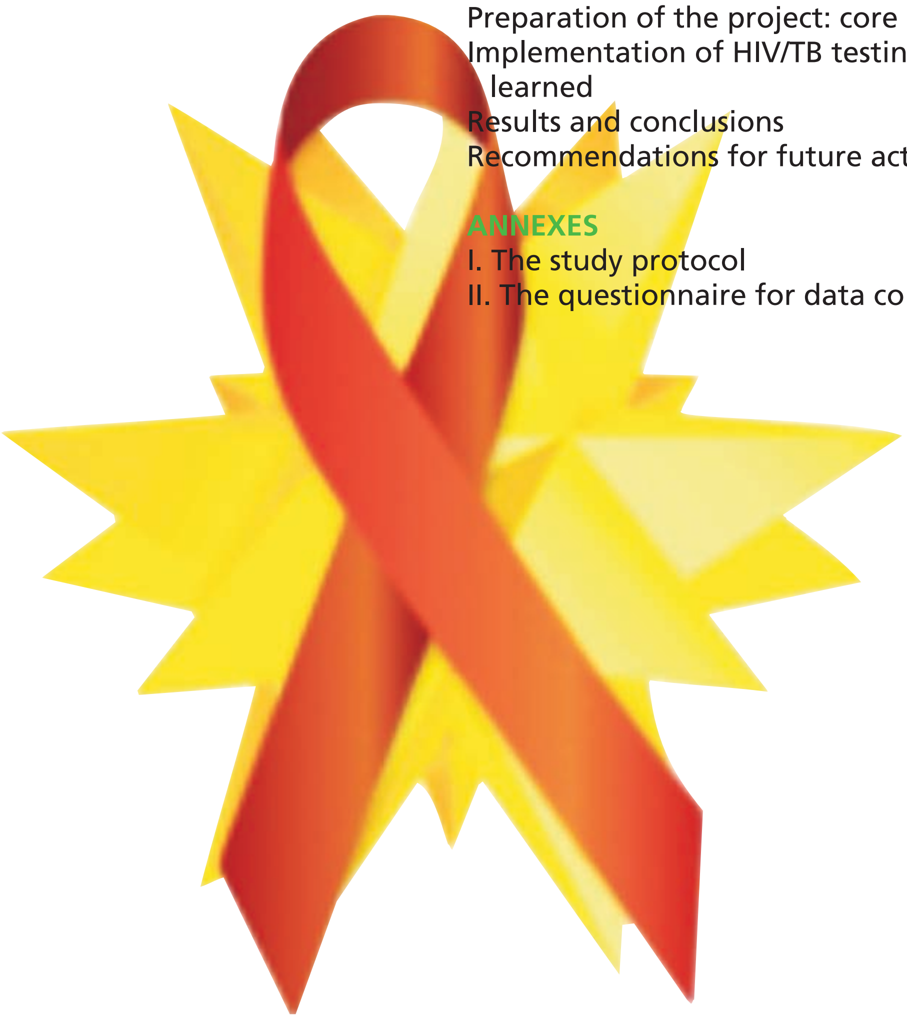

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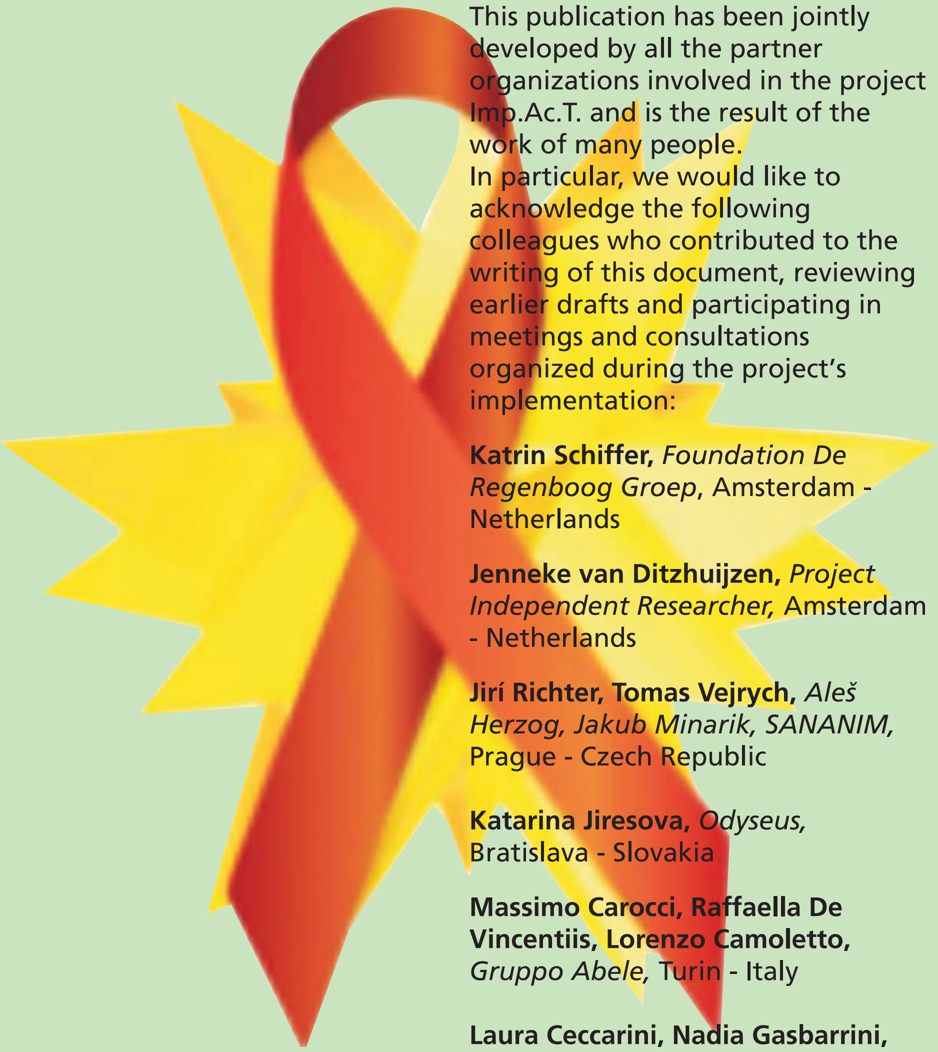

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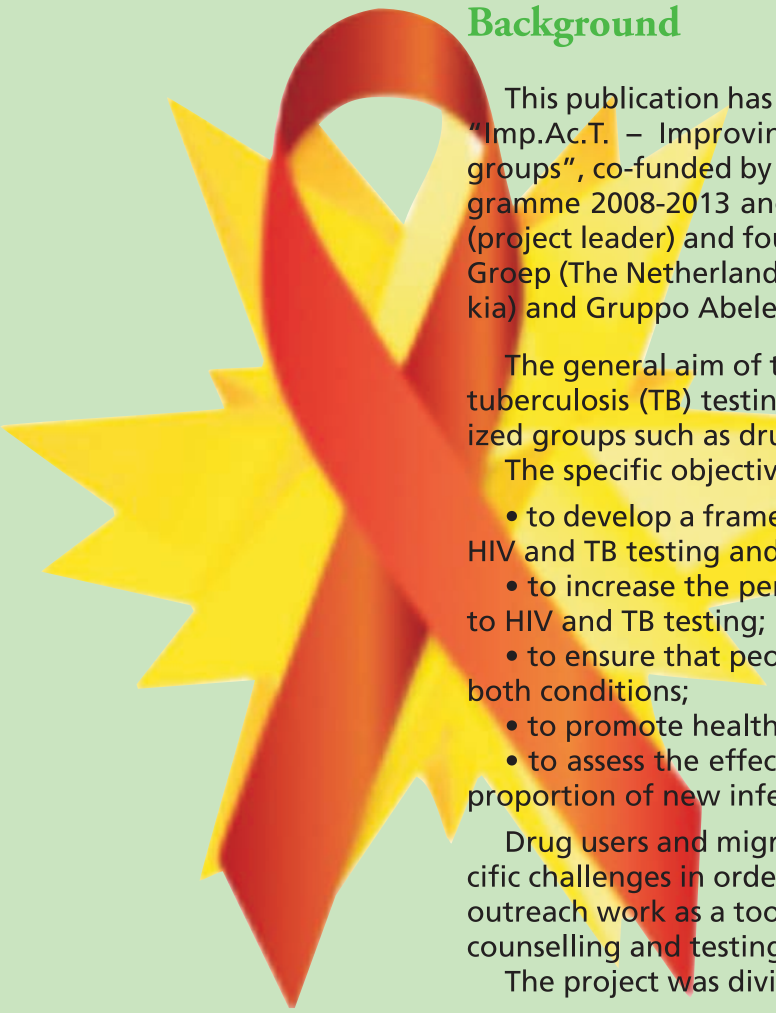
Introduction



Background

This publication has been developed in the framework of the project "Imp.Ac.T. – Improving Access to HIV/TB Testing for marginalized groups", co-funded by the European Commission under the Health Programme 2008-2013 and implemented by the Foundation Villa Maraini (project leader) and four associated partners: Foundation De Regeboog Groep (The Netherlands), Sananim (Czech Republic), OZ Odyseus (Slovakia) and Gruppo Abele (Italy).

The general aim of the project was to broaden the access to HIV and tuberculosis (TB) testing, prevention, treatment and care for marginalized groups such as drug users (DUs) and migrants DUs.

The specific objectives were:

- to develop a framework and model to improve the effectiveness of HIV and TB testing and counselling among DUs and migrants DUs;
- to increase the percentage of DUs and migrants DUs having access to HIV and TB testing;
- to ensure that people living with HIV and TB receive treatment for both conditions;
- to promote healthier ways of life and risk reduction among DUs;
- to assess the effectiveness of street HIV and TB testing in terms of proportion of new infection identified.

Drug users and migrants DUs have specific needs and encounter specific challenges in order to get tested and treated. The project has used outreach work as a tool for promoting a new kind of provider-initiated counselling and testing, specifically tailored to hard-to-reach groups.

The project was divided in three main phases:

1) development of common tools for street HIV and TB testing among DUs and migrants DUs;

2) implementation of HIV and TB rapid tests in low-threshold facilities for DUs and migrants DUs;

3) comparative analysis and assessment of the effectiveness of such intervention.

The first phase has consisted in the exchange of experience and information among the partners, analysis of main weakness and strengths of current strategies for HIV/TB testing of risk groups and definition of key health determinants for monitoring and reporting of new diagnosis among these target groups.

The methods used in the second phase has included the conduction of training sessions for the staff of each partner organization and then, the provision of HIV and TB tests for DUs and migrants DUs attending low-threshold facilities in Rome, Turin, Bratislava and Prague. HIV rapid test and TB clinical screening has been offered in street units, drop-in centres, needle exchange points, substitution treatment facilities, for a final number of around 2500 people tested.

For the TB suspected cases, a sputum sample has been collected and sent to specialized clinics for laboratory examination.

Those resulted preliminary positive to HIV and TB testing have been referred to specific clinical centres for confirmatory analysis and eventually, treatment.

The third phase has included the analysis of all collected demographical, epidemiological, clinical and laboratory data from each partner (number of persons tested, number of HIV and TB-positive, number of persons receiving treatment after testing) and the assessment of this kind of intervention in terms of a wider access to testing for marginalized groups and timely identification of new infections.

Scope and purpose

This publication has been jointly developed by all the partner organizations, on the basis of the experience acquired during the implementation of the project Imp.Ac.T. It is not intended as a guidelines giving technical instructions on how to provide HIV and TB testing in low-threshold services for drug users, but rather as a presentation of best practices and lessons learned that may help other organizations willing to carry on similar programmes in their own countries.

The recommendations presented in this manual were collected through a self-evaluation process undertaken by the implementing organizations, during which they were requested to think about and reflect on what worked and what didn"t work so well during the planning and implementation of HIV/TB testing programmes.

The manual is structured according to the project implementing phases, starting from the development of study protocol and working tools to the collection and analysis of all collected data. Moreover, the last two chapters include a presentation of main results and outcomes, as well as lessons learned and recommendations for future actions.

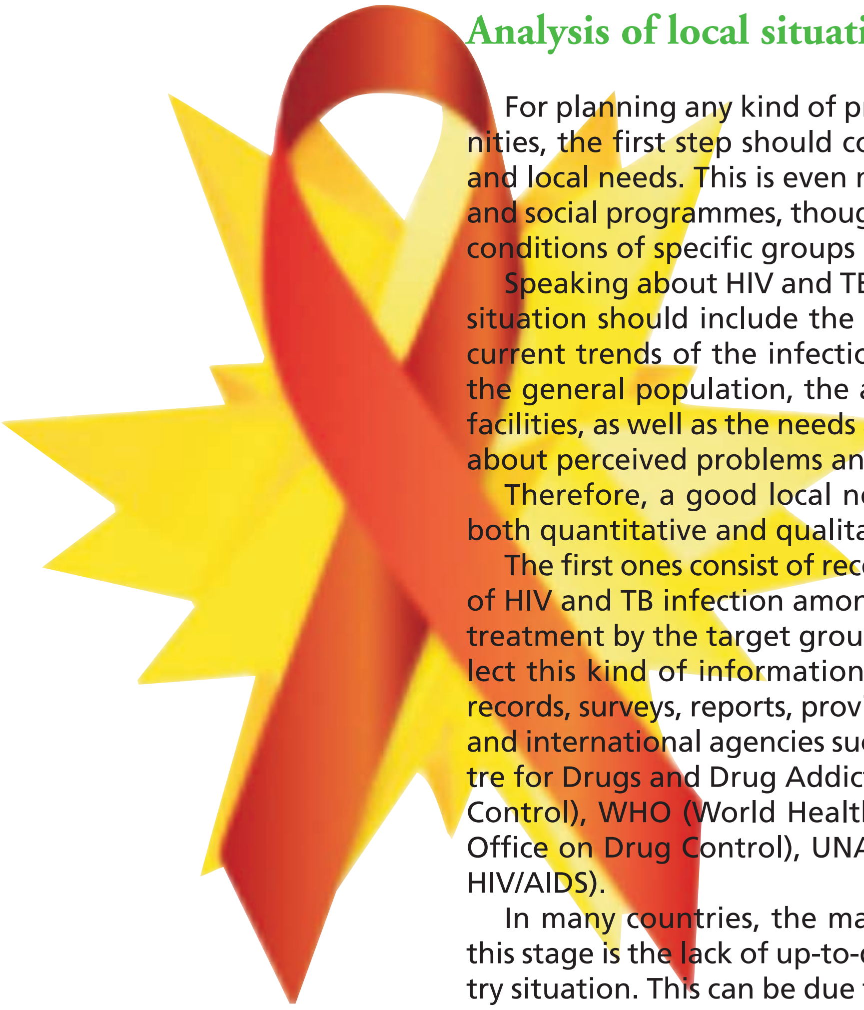
We think that this guide manual can represent a useful tool for other professionals working with most vulnerable groups and willing to implement HIV and/or TB testing programmes. Our aim is to improve knowledge and information of programme managers and planners, health care service providers, social and outreach workers about HIV and TB counselling and testing, in order to strengthen skills and capacities required to effectively offer such important service to drug users, migrants and other marginalized groups in non-medical settings.

By using this manual, project operators will gain useful recommendations on the following:

- Development of testing protocol and working tools
- Key elements of HIV and TB testing provision among DUs and migrants DUs:
  - approach and recruitment
  - pre-counselling and risk assessment,
  - post-counselling for both negative and positive results and risk reduction
- Building up of referral system to treatment centres and other health-care services
- Basic skills on data collection and recording

Chapter 1

Development of common methodology for HIV and TB testing



Analysis of local situation and national legislation

For planning any kind of projects or activities involving local communities, the first step should consist in the analysis of the local situation and local needs. This is even more important when approaching health and social programmes, thought for improving the well-being and living conditions of specific groups of people.

Speaking about HIV and TB testing programmes, the analysis of local situation should include the collection of information about past and current trends of the infections among the specific target groups and the general population, the availability of testing, treatment and care facilities, as well as the needs and opinions of the selected target groups about perceived problems and constraints.

Therefore, a good local need assessment requires the collection of both quantitative and qualitative data.

The first ones consist of recent data on drug use, incidence/prevalence of HIV and TB infection among the target groups, access to testing and treatment by the target group, mortality rate. Examples of tools to collect this kind of information are epidemiological and demographical records, surveys, reports, provided by both national and local institutions and international agencies such as EMCDDA (European Monitoring Centre for Drugs and Drug Addiction), ECDC (European Centre for Diseases Control), WHO (World Health Organization), UNODC (United Nations Office on Drug Control), UNAIDS (Joint United Nations Programme on HIV/AIDS).

In many countries, the main difficulty that may be encountered at this stage is the lack of up-to-date and reliable official data on the country situation. This can be due to the use of not adequate data collection systems or to the low interest of governments on issues such as drug abuse and related health diseases. In particular speaking about TB, the availability of up-to-date data on incidence/prevalence of the disease among drug users as well as the general population can be very low, due to the fact that this disease is not considered at the moment a main public health threat in several European countries.

As reported by SANANIM, the main problem for them has been *"the lack of information about TB seroprevalence among IDUs in Czech Republic, as well as the lack of knowledge and information about TB testing"*.

Indeed, before planning the testing methodology for HIV and TB as well as for other infectious diseases, it is fundamental to collect information about the current national legislation on testing procedure, in order to plan activities which are in line with the national public health regulations.

Our project gives a practical example of the importance of having such information. The common methodology for TB testing planned within Imp.Ac.T was not in line with the Czech legislation regulating the provision of medical services in low threshold services, which obliges service providers to refer immediately any suspected case of infectious disease to specialized health centre. Therefore, social services are authorized to do only assessment of TB symptoms in low-threshold facilities, but not sputum smear collection and analysis. It would have been better if this information was available before the start of the project, rather than after the beginning. It is important to choose the project partners based on accurate "baseline" information of, in this instance, TB and HIV prevalence; as well as local legislation and local activities (other projects existing programmes aimed at similar goals).

In Imp.Ac.T. the planned TB methodology had to be adapted to the national rules in Czech Republic.

In order to cope with the problem of lack of statistical and epidemiological data, it is highly recommended to use other sources of information, such as local and national experts that can act as key informants. They can be local healthcare authority representatives, policy makers, researchers, managers/directors of low-threshold facilities, with good knowledge in the field of drug abuse, HIV and/or TB situation in the country. As reported by SANANIM and Odyseus, what worked well for them in the collection of data was the "*consultation with experts and National Focal Point"* and *"discussions with different experts and stakeholders"*.

The involvement of relevant experts and stakeholders may bring several advantages not only in terms of new acquired information and knowledge, but also in terms of technical support and fruitful collaboration throughout the project implementation.

As for qualitative data, they consist in opinions, point of views, experiences of key informants and target group members about health behaviours, availability and access to testing and treatment facilities, rate of use of safe lifestyles and preventive measures regarding HIV and TB. Examples of tools to collect qualitative data include focus groups and face-to-face interviews.

Of course, the collection of such kind of information requires trustful and long-lasting relationship with the target group, i.e. drug users. At this regard, the long experience of the implementing organizations in working with drug users acquires an added value and represent a fruitful way to access to a wider and sometimes hidden range of information concerning the issue analysed.

> *"What worked well for us in the collection of information was the long-term work in this field, since we already had most of the documents read before/during the project as it is part of self-learning process, as well as communication with other experts in the field"* (Odyseus).

Development of study protocol and working tools

The development of a testing programme always implies a detailed planning of procedure and tools to be used. This is even more important when the programme includes the combined testing of two or more infections and it is planned to be carried out in different contexts and places.

The study protocol should include a description of participants (number, eligibility and exclusion criteria), details of the intervention or therapy that participants will receive (schedule of tests, procedures, medications and dosages), what data will be gathered and how this information will be handled and assessed.

The development of a detailed study protocol primarily aims to lay down the rules for all partners and to ensure that the resulting data will be significant and reliable.

In addition, it is needed for checking the study's feasibility and obtaining approval of ethical committee(s).

The protocol outline should contain the following points:

1. Background and justifications.
2. Objectives and research questions.
3. Methods (study design and implementation).
4. Study population (selection, recruitment, sample size).
5. Study procedures and assessment (data definition, data collection, data handling and analysis).
6. Ethical considerations (respect of privacy, confidentiality, security of data storage and protection).
7. Project management (participating institutes, responsibilities and tasks of each partner).
8. Timetable.

(*See Annex 1. for the full version of the IMP.AC.T. study protocol*)

Referring to HIV and TB testing programme, it is crucial to include in the study protocol a detailed description of methods and tools used for testing as well as for data collection.

As already said, the testing procedure must be in line with the national legislation of the country where the programme is going to be carried out, therefore it is highly recommended to involve national and local experts in the development of the protocol.

In particular for TB, the selection of the testing procedure should be discussed with representatives of public bodies and/or TB clinical centres, since the procedure for testing must follow and respect all standard for security of participants, service providers and general population.

According to our experience, during the development of the study protocol it was very useful "*the technical advice of experts from the National Institute on Infectious diseases*" (Villa Maraini Foundation) and "*the collaboration with medical doctors of a TB clinical centre*" (SANANIM).

In addition, it is advisable to review current international guidelines on HIV and TB testing and consult with recognized experts in this field. This can be done through the setting up of an Advisory Board composed of representatives of international agencies and relevant national institutions, willing to provide technical advice on testing methods and tools. The involvement of such experts can be useful for better understanding limits and advantages of each testing methodology and identify the one which is more appropriate for the selected target groups and for achieving the project objectives.

Referring to our experience, the consultation with international experts was extremely useful for the definition of the TB testing methodology. Indeed, the first method proposed for detection of TB infection was the tuberculin skin test (Mantoux), to be provided to drug users with clinical symptoms of TB.

However, the consultations with different experts and review of current international guidelines raised doubts about the use of Mantoux, due to its low specificity and high possibility of having false positive or false negative. Moreover, in some countries such as the Czech Republic and Slovakia most of the people are vaccinated for TB, therefore would have resulted positive to the Mantoux test.

Consequently, it was decided to select a methodology which would facilitate the detection of active (and not latent) TB infection in drug users, such as the conduction of clinical screening and sputum smear examination.

In order to ensure that the collected data and results of the study will be significant and reliable, it is fundamental that a single standard protocol is used by all the implementing organizations. Therefore, the procedure for testing must be described in details, starting from the recruitment of target group to the analysis of collected data.

In particular, it's important to give a clear definition of the people to be enrolled in the study, indicating main characteristics, eligibility criteria and sample size.

Talking about projects targeting drug users, it is recommended to clarify which typology of drug users are addressed by the study (problematic drug users, occasional users, users of any kind of psychoactive substances including alcohol, etc.).

This represented a critical issue within Imp.Ac.T. From a research point of view it was necessary to narrow down the study sample from the broadly defined target group of "drug users and migrant drug users", therefore we started out with including only "problem drug users". During the course of the project, it became clear that this strict definition lead to exclusion of a large part of usual clients of the services from the project (alcoholists for Gruppo Abele, sex workers for Odyseus, occasional users for Villa Maraini). At the end, the problem was solved with a "compromise": the testing was offered to all clients of the selected low-threshold services, but the data analysis would focus on problematic drug users.

Establishment of regular monitoring tools

In consideration of the above, i.e. the difficulty that can be encountered when developing a common methodology to be used in different contexts, the set-up of a regular monitoring system acquires a major value.

The monitoring should be an on-going process aimed to a continuous assessment of project implementation in relation to agreed schedules and indicators. It should be worked out to keep a check of planned activities over a period of time, in order to give early warning of possible problems and difficulties and facilitate timely adjustments and changes.

First of all, the monitoring should be performed using common design tools such as the Logical Framework Matrix, Milestones table and Activities lists per work package.

These are internationally widely used and appreciated methods that allow to have a clear overview of project objectives, verifiable indicators (expected changes in variables), producing outputs/deliverables and methods or sources of information to verify their impact on beneficiaries.

To make information on progress available right from the early stages of implementation and throughout the project cycle, indicators need to be structured, i.e. must be divided in process, output and outcome indicators.

At this regard, it’s important to set up methods for collecting data and managing project records, so that the data required for indicators are compatible with existing statistics and are similar in every country where the project is implemented.

When developing the common methodology for HIV/TB testing, particular attention should be given to the arrangement of common working tools for data collection and record-keeping. Within Imp.Ac.T., all partners have used the same form for recording the number of people contacted and tested (the Response Monitoring Form), and the same online database for entering the data of people tested. The use of these common tools has allowed to have comparable data in all the four project sites, thus facilitating the monitoring of activities and analysis of the response of beneficiaries to the services provided.

As reported by SANANIM, “*we mostly valued common methodology on data collection and elaboration, since it allowed data consistency and comparability*”.

In addition to project management tools, a good monitoring system should also include coordination and proactive collaboration among all involved parties, final beneficiaries and funding agencies. This can be ensured through the establishment of regular communication tools, such as progress reports, audio conferences, meetings, which serve to report about the level of progress of activities as well as barriers and problems that might be encountered.

According to our experience, it is more productive to exchange information through direct contacts such as meetings and audio calls, instead of writing reports, because it gives the possibility to discuss and analysis more in details critical issues and agree on shared solutions and adjustments.

As demonstrated by our experience, the constant coordination among all the partners and with the funding agency has allowed to identify main obstacles in the implementation of activities and find in time the most proper solutions, such as changes of TB testing methodology (SANANIM) or modification of the budget (all the partners).

In conclusion, our experience show that the development of a common methodology to be used by different organizations in different countries represents a challenging work, requiring adaptation to local contexts and needs and flexibility in case of unpredicted problems and obstacles.

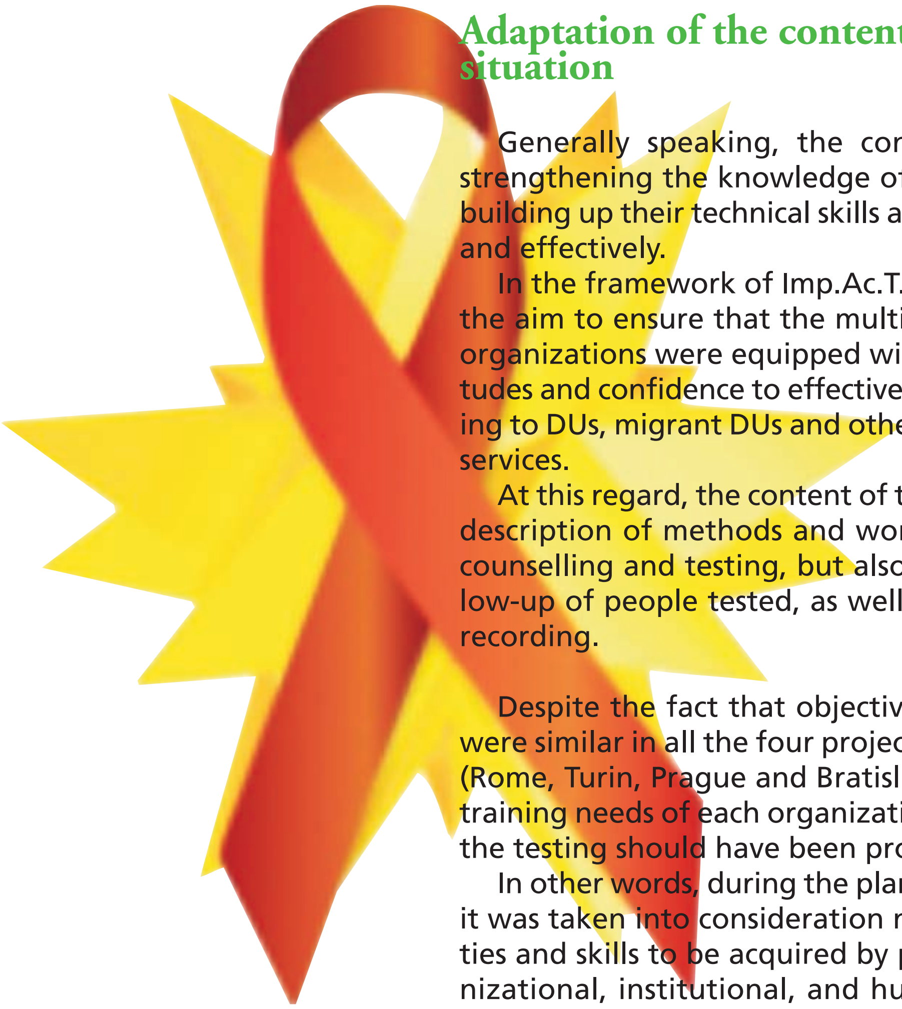
> *"The development of a common methodology was very challenging, because it put us in face of strengths and weaknesses in each countries and cities and allow us to learn each other"* (Gruppo Abele).

Kick-off meeting in Rome

Meeting in Prague

Chapter 2

Training courses on HIV and TB testing in low-threshold services for DUs



Adaptation of the content to training needs and local situation

Generally speaking, the conduction of training courses aims at strengthening the knowledge of participants on a specific topic and at building up their technical skills and abilities in order to perform properly and effectively.

In the framework of Imp.Ac.T., training courses were conducted with the aim to ensure that the multi-disciplinary staff of the implementing organizations were equipped with the necessary skills, knowledge, attitudes and confidence to effectively offer HIV and TB counselling and testing to DUs, migrant DUs and other marginalized groups in low-threshold services.

At this regard, the content of the training included not only a detailed description of methods and working tools for the provision of HIV/TB counselling and testing, but also key elements for recruitment and follow-up of people tested, as well as information on data collection and recording.

Despite the fact that objectives and content of the training courses were similar in all the four project sites where they have been organized (Rome, Turin, Prague and Bratislava), they were adapted to the specific training needs of each organization as well as to the local context where the testing should have been provided.

In other words, during the planning of training objectives and content it was taken into consideration not only the overall knowledge, capacities and skills to be acquired by participants, but also the existing organizational, institutional, and human capacity gaps that needed to be addressed by the training.

This is important for ensuring that both trainers and participants clearly understand what they are aiming to. The main risk in not following the above-mentioned recommendation is that training might not be relevant to key aspects of the work of participants and consequently, lose its effectiveness.

For example, in Prague and Bratislava the training focused in particular on how to conduct TB testing, since this was a new topic for them and the staff had very low experience and knowledge about this issue. Therefore, particular attention was given to the explanation of how to conduct a TB clinical screening and how to refer suspected cases to TB clinical centres.

In Rome, more time was dedicated to the presentation of working tools such as the Response Monitoring Form and the Questionnaire for data collection and to the simulation of their use with clients of low-threshold services. This was very useful for identifying strengths and limits of such procedure and equipping participants with the necessary skills and know-how.

The assessment of training needs, meaning the evaluation of current capacities and skills of participants on the one hand, and the definition of what skills and knowledge they need to acquire on the other hand, it's a fundamental step to ensure the achievement of the training overall aim.

Trainers and organising staff are strongly recommended to find out what range of experience and what level of knowledge participants might have about the subject of the training, in order to provide a good balance between old and new information.

Moreover, it is important to have an understanding of the participant's training needs so that these can be adequately addressed during the workshop.

For organizations with a long working experience with drug users, topic such as HIV testing and counselling should be part of a long-term system of continual training, to constantly update knowledge and skills in line with latest international guidelines and recommendations. In particular, the provision of pre- and post-counselling both for HIV and TB is a very sensitive issue which requires specific professional skills and capacities, as well as a deep knowledge of the topic and all its related issues (medical, social and personal aspects of being HIV and/or TB infected). For this reason, it is advisable to dedicate enough time to train staff members on pre- and post-counselling, maybe organizing specific trainings on this topic.

As for the conduction of the HIV testing, it is important to provide service workers with detailed information about the functioning of rapid test (main characteristics, test procedure, interpretation of results) and to give a practical demonstration of how to use it. The use of interactive approaches will positively affect the learning process of participants, facilitating the acquisition of practical skills and fostering a more complete knowledge of the issue.

As reported by Gruppo Abele, *"to make the staff ready for administering the testing, you must provide a practical demonstration of the rapid HIV test and explore together the part of the pre and post counseling, which requires a deeper preparation".*

With regards to TB testing, when planning the content of the training course it's important to verify first of all the general level of knowledge of participants about TB infection and disease. Indeed, in countries with low incidence of TB the level of information about this disease is very poor, since it does not represent a major public health issue. Therefore, even health care providers may have very basic knowledge about tuberculosis and no information about testing methodology and approach.

Making an assessment of the level of knowledge of participants about TB will allow to identify their training needs and define the training content according to this.

In any case, it is always advisable to provide trainees with information about different forms of TB (latent infection, active disease, pulmonary TB, etc.) and way of transmission, as well as different methods for testing and TB diagnosis.

Since the methodology for TB testing used in the framework of Imp.Ac.T. has been the clinical screening and the sputum analysis, particular focus has been given to the explanation of how to conduct a clinical screening for TB and how to collect a sputum sample for laboratory examination. With regard to the clinical screening, it's indispensable to explain what are the main risks for TB infection and what are the clinical symptoms of TB; regarding the collection of sputum sample, it's fundamental to dedicate some time to the presentation of the procedure for safe sputum collection, cough etiquette and procedures to reduce the risk of spreading infection through sneezing and coughing.

Finally, in the case of training courses organized in the framework of a specific programme with the aim to train the operational staff, it is important to clearly explain participants the project objectives, planned activities and expected outcomes and results.

In conclusion, the definition of the content of a training course on HIV and TB testing should take into account the following aspects: training needs of participants (what skills and knowledge they need to acquire); local situation and context where the testing will be performed; specific objectives and methodology of the planned testing programme.

> *"Trainings are very important for increasing the knowledge, skills and professionalism of the staff. Any similar project should be accompanied by series of trainings"* (Odyseus).

Criteria for selection of participants

The selection of participants for a training course is a key issue, since the approach in which the content of the training is delivered may be different depending on whether the audience consists of social workers, psychologists or counsellors, nurses or other health professionals.

Talking about training courses on HIV/TB testing in low-threshold services for drug users, the audience may be composed by all the above mentioned professionals, having each of them a specific role in the testing provision.

The criteria for selecting participants should be then based first of all on the specific context where the testing will be provided and on the methodology which will be used.

If the testing is going to be offered to drug users clients of low-threshold services, it is fundamental to involve in the training course social and outreach workers, since they have a main role in the approach and recruitment of people for testing.

On the other hand, the typology of the testing methodology is important for defining the need of involving in the training medical doctors, nurses or other health professionals.

In some countries such as Slovakia, the HIV rapid test should not be necessary provided by health professionals, but can be administered also by social workers, while in other countries such as Italy this is not allowed. Consequently, the training on how to administer the testing must necessarily involve doctors or nurses if they are the only professionals allowed to provide it.

Of course, motivation is a key element that must be taken into serious consideration when selecting participants for a training. Participants must be interested in the subject and must see a pragmatic benefit of attending that specific course to improve their skills and performance. A highly motivated participant is a trainee who learns what is taught in the training course and implements properly the knowledge acquired.

This is particularly important when attending a training course on HIV and TB testing and counselling, due to the complexity and high sensitivity of this issue. Participants must be sure of their willingness to work in this kind of programmes, since it requires high level of motivation and commitment. At this regard, it is always advisable that trainers try to assess the personal capacities and attitudes of participants towards this specific topic, in order to avoid any kind of prejudices and stigmatization.

An advantage is if the trainees are already experienced workers (preferably if ex-drug users), so they do understand the language and daily reality of the target populations and do not have unrealistic expectations (e.g.: people returning for the sputum results within the week, as meanwhile they could be imprisoned or other situation can change their priorities in life).

In the case of training courses organized with the aim to train the staff that should be involved in the implementation of a specific project, such as the case of Imp.Ac.T. it is highly recommended to select people that certainly will be the ones carrying out the activities. This will ensure the achievement of training objectives and guarantee that the new knowledge and skills acquired by participants will be used properly and effectively.

In conclusion, participants should be selected according to their willingness to participate, their affinity with the subject discussed, their interest in being involved in HIV and TB testing programmes. Moreover, it is important that the selected trainees have the right knowledge, skills and attitudes for the training; otherwise, although scheme and contents are well-designed, the training may not meet its objectives.

Criteria for selection of trainers

Trainers play a critical role in any training program, since they are the key to effective learning; therefore, they must be chosen carefully in line with local needs, cultures and available resources.

Competencies and skills are the basis upon which trainers should be evaluated and selected. When talking about training courses on HIV and TB testing among drug users, these competencies must include a thorough knowledge and understanding not only of HIV/AIDS and TB infection, pre and post counseling, testing methodologies, but also of drug addiction and harm reduction programmes for drug users. This knowledge is particularly important if the training course focuses on the provision of testing in low-threshold services, such as in the case of our project, since a relevant part of the training should include the methodology for outreach approach and recruitment of clients, as well as for their follow-up and referral to health care services. These topics cannot

Training course in Rome

be properly treated if the trainers do not have a long working experience in the field of drug abuse.

Therefore, for the conduction of training courses on HIV/TB testing among drug users, it is advisable to select as trainers the following specialists: psychologists/social workers (for the modules on counselling); health professionals (for the modules on HIV rapid test and TB clinical screening); social workers (for the modules on recruitment and motivation of clients to testing).

On the other hand, the complexity and multifaceted aspects of drug use and correlated HIV and TB infection requires a multidisciplinary team of trainers with different personal and professional background, in order to provide participants with multiple approaches, ideas and solutions.

This is highly recommended when the training course includes topics such as the collection and management of personal data of clients. In these cases, it would be very useful to have in the team of trainers a person with specific competencies and knowledge, such as a researcher, able to provide participants with adequate information and skills. According to our experience, the involvement in the training course of a researcher able to train participants on how to conduct interviews and questionnaires with drug users for data collection would have avoided the raising of conflict of roles among social workers during the carrying out of testing activities.

As reported by Gruppo Abele, "*during the training course we missed to dedicate a specific time on the issue of conflict of roles for social workers while acting as interviewers".*

Also the training skills should be taken into account, when choosing for the trainers. The content of the training is one important segment, however ability to train other people requires different set of skills.

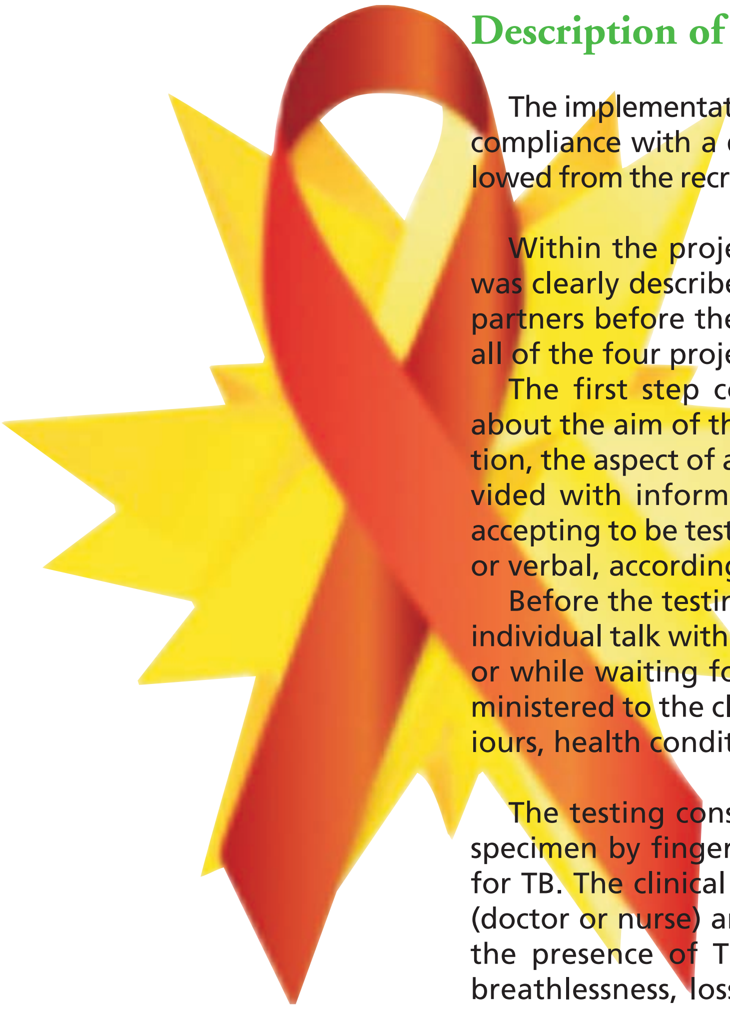
If the selection of trainers from its own organization is good in terms of a deep knowledge of the target group and a better understanding of the staff training needs, an active and balanced involvement of different stakeholders as external trainers can have several benefits. Main stakeholders are to be considered other civil society organisations, public health institutions, local, national and international authorities.

On the one side, they can bring a fruitful contribution to the improvement of skills and capacities of trainees, thanks to their knowledge and expertise. On the other side, the dialogue with stakeholders might lead to a fruitful share of opinions and ideas, and can contribute to improve cooperation and strengthen networks and professional alliances.

As reported by SANANIM, *"one of the main benefit of the training was the establishment of cooperation with the doctors from tuberculosis clinic, because she presented new information and we discussed on how to facilitate the access to health care services for our clients".*

In conclusion, the development of a proficient learning group of participants requires the organisation of a strong team of trainers with different and complementary knowledge, skills and professional experience. It will give an added value to the training and promote a deeper understanding of the overall issue.

Chapter 3
Provision of HIV and TB counselling and testing



Description of the methodology

The implementation of testing programmes requires the definition and compliance with a detailed procedure, indicating all the steps to be followed from the recruitment of clients to the communication of test results.

Within the project Imp.Ac.T., the procedure for HIV and TB testing was clearly described in the study protocol jointly developed by all the partners before the starting of the testing phase, and was followed in all of the four project sites.

The first step consisted in informing clients recruited for testing about the aim of the project, the procedures of testing and data collection, the aspect of anonymity and privacy. At this regard, they were provided with information leaflets on HIV and TB infection, and those accepting to be tested were asked to give the informed consent (written or verbal, according to the local rules).

Before the testing, all clients received pre-counselling in the form of individual talk with a counsellor/psychologist. During the pre-counselling or while waiting for the HIV rapid test result, a questionnaire was administered to the client, with the aim to collect data on lifestyles behaviours, health conditions and history of HIV and TB testing.

The testing consisted in the provision of HIV rapid test with blood specimen by finger stick (DETERMINE HIV 1-2) and a clinical screening for TB. The clinical screening was conducted by an health professional (doctor or nurse) and aimed to identify suspected cases on the basis of the presence of TB symptoms (prolonged cough, fever, chest pain, breathlessness, loss of weight, fatigue) and/or TB risk factors (provenience from countries with high TB prevalence, close contacts with persons known or suspected to have TB, persons with reactive HIV rapid test, persons infected with HIV or with other medical risk factors).

Those individuals with one or more clinical symptoms or with other risk factors were considered suspected cases and were requested to give a sputum sample to be sent to clinical centres for laboratory examination.

The communication of test results was always accompanied by post-counselling.

For those with reactive HIV results, a follow-up appointment was scheduled at dedicated health care services for confirmatory blood test.

As for TB, in case of positive result of the first sputum sample the staff arranged a follow-up appointment to the clinical centres for the collection of a second sputum sample and further diagnostic workup for TB; in case of negative result, a second sputum sample had to be collected and only in case of positive result the client was referred to clinical centres.

As for the project partner SANANIM, since the national legislation obliges service providers to refer immediately any suspected case of infectious disease to specialized health centre, they conducted the TB clinical screening for identifying suspected cases, but instead of collecting a sputum sample in their low-threshold facilities, they referred the suspected cases directly to specialized health facilities for further examination (X-ray).

According to our experience, having a step-by-step description of the procedure to be followed during the testing provision is very useful. In particular, it helps to clearly define roles and tasks of each staff member and avoid conflict of roles or overlapping.

The implementation of an HIV and TB testing programme in low-threshold services requires the involvement of different professionals, each of them with a specific role: outreach/social workers for approaching, informing and motivating the target group to get tested; psychologists/counsellors/social workers for providing pre- and post-counselling; doctors/nurses for administering the HIV rapid test and TB clinical screening.

This definition of roles is important for ensuring the good quality of the provided services and facilitating collaboration and team work.

Volunteers can be also involved in this kind of programmes, but it is important to bear in mind that they cannot replace professionals in the provision of services such as counselling and testing. Moreover, it is fundamental that they receive specific training on drug use and related infectious diseases, in order to get a comprehensive knowledge of the topic and have a better work performance.

As reported by the outreach workers of Villa Maraini, *"a specific training should be done for volunteers, in particular regarding the approaching and recruitment of clients, in order to make their work more effective and valuable"*.

Of course, when offering the testing to drug users in low-threshold facilities such as street units, it is not always easy to follow step-by-step the indicated procedure, due to the specific characteristics of the clients of this kind of services.

For example, the distribution of informative leaflets should be accompanied or replaced by the verbal explanation of aim and procedures of testing, because a high percentage of approached clients would rarely read the leaflets.

For clients who are in a hurry and don't want to waste much time, it might be necessary to speed up the procedure, for example administering the questionnaire while waiting for the HIV test results.

In conclusion, it is always recommended to be flexible and ready to adapt the work to particular needs, situations and circumstances, as far as the pre- and post-counselling will not be left out or minimized.

Criteria for selection of locations for testing

Generally, the selection of places for implementing activities depends on the specific target groups to whom the project is addressed. In other words, each organization selects the places/services where the specific target groups can be found.

For the provision of testing programmes among marginalized groups such as problem drug users, the selection of places must inevitably take into consideration all the so called "low-threshold services".

The term "low-threshold" is used to describe a setting which aims to facilitate drug users" access to social and health services delivery. To lower the threshold of access, such agencies choose specific locations and opening hours, require little bureaucracy, often no payment, no need to have official documents and are not linked to an obligation of the client to be or to become drug-free. They target current users, "hard-to-reach" groups, high-risk groups among drug users and experimental users. They can play an important role for the delivery of "survival-oriented" services to problem drug users, like shelter, hygiene, food, sterile injecting equipment and medical care. They increasingly deliver treatment services as well.

They are core settings for disseminating health promotion messages and increasing safer use information and skills among those who use drugs either experimentally or in a dependent or problematic way[1].

Typically, low-threshold services include street units, needle-exchange points, drop-in or contact centres, night shelters, substitution treatment programmes, etc.

Within Imp.Ac.T., the places selected for the provision of testing have included all these types of facilities, managed by the implementing organizations as well as by other local organizations/institutions. In Rome, the testing has been offered in all the low-threshold services managed by Villa Maraini Foundation (drop-in centre, street units, clinical centre for substitution therapy) and in two public centres for substitution treatment. In Turin, testing has been provided in the drop-in centre of Gruppo Abele and in mobile unit and night shelters managed by other local organizations. In Bratislava, it has been offered in the mobile unit of Odyseus and in a night shelter for homeless managed by the organization DEPAUL Slovensko. In Prague, testing has been offered in all the low-threshold facilities of SANANIM (outreach unit, contact centre and substitution programme) and in two other facilities managed by another local NGO (contact centre and methadone substitution programme).

The collaboration with other local services and facilities is useful for enlarging the number of potential beneficiaries and facilitating the access to testing to high-risk groups of drug users such as homeless. It is highly recommended to select places where the testing has never been offered, or is not provided on a regular basis, in order to reach people who most probably have never been tested or may prefer to get tested in non-medical settings.

In addition, the cooperation with other local low-threshold services can bring benefits also in the long-term, promoting the set up of networks and referral system which facilitate the access of drug users to the required care, support and treatment programmes.

Of course, these networks are highly effective and fruitful if the cooperation among local actors is well-functioning and supported by a joint willingness to cooperate. This is not always easy to reach, in particular when talking about the cooperation with public health services, which may have different opinions and methods of working with drug users.

As experienced by Villa Maraini, *"very few public centres for substitution treatment were willing to cooperate. It seems that NGO's are still seen as threat and competitors and not as potential partner".*

Recruitment of clients/target groups for testing

The selection of places for the provision of testing should take into consideration the importance of having adequate tools and resources for approaching and recruiting clients for testing. In fact, the recruitment of target group members is a crucial step in the implementation of testing programmes and can represent a major problem if not done in the most adequate way.

When talking about testing programmes targeting drug users and other marginalized groups, it is highly recommended that they are firstly approached by outreach and/or social workers of the low-threshold facilities, who will offer them the possibility to be tested explaining the benefits and advantages of such service.

During the approaching and recruitment phase, staff members can use the "Motivational interviewing" method, combining elements of empathy and negotiation with the aim to improve patient's motivation toward knowing his/her own health status.

The role of social workers is fundamental, because they represent the link between the target group and the health-care services, being their relation with clients based on trust and confidence. Consequently, they can better than others motivate drug users toward testing and other safer behaviours.

As reported by Odyseus, one of the problems they had during the recruitment of clients was due to the presence of a nurse, who was a new staff member and not known by the regular clients of their service.

"The nurse was a stranger for many people and it took time for people to start trust in her".

Mobile unit in Prague

On the contrary, in Turin the presence of a medical doctor for the provision of HIV and TB testing has facilitated the approaching and recruitment of clients, who saw it as a good opportunity to have a medical screening and receive reliable information about the two infections. As reported by Gruppo Abele, *"people reacted very positively to the presence of a doctor, since it gave them the feeling that their own health status was taken into serious consideration and used this opportunity to ask for information and recommendations on their health".*

Drop in centre in Prague

The selection and approach of the target groups should be completely random. Information about the provision of testing should be widely disseminated in the involved low-threshold services, through announcement on notice-board and distribution of informative leaflets among the clients. It is important to assure that information about HIV and TB testing possibilities will reach a wide spectrum of target group members, in order to raise personal interest in being tested.

According to what experienced during Imp.Ac.t. even if all the above mentioned conditions are respected, the recruitment of drug users for testing can be very problematic. This is mainly due to the particular working conditions in low-threshold services and to the specific characteristics and needs of the target group.

The offering of testing in mobile street units, for example, can be affected by weather conditions, since during winter time the number of clients decreases significantly, and when the temperature is too cold (below 0° C) or too hot (above 30° C), the provision of testing in a van can be problematic.

Moreover, the provision of testing on a regular basis can be affected by several unforeseen events/circumstances such as the lack of workers, the unexpected close down or unavailability of some facility, the difficulty in hiring medical staff for the administration of TB testing.

> *"Not all spots (facilities) do have one specific person, being responsible for the testing. This should be changed"* (SANANIM).
>
> *"The target group of DU's is unattractive and not many nurses like to work with and for this group"* (Odyseus).

On the other side, it's necessary to bear in mind the specificity of our target group, i.e. drug users attending low-threshold services. This includes problem drug users and "at-risk" groups among regular and occasional users, such as sex workers, homeless, illegal migrants, alcoholics. Motivating these clients toward testing is very hard, because they have other priorities and needs: they are in a hurry and don't have enough time for getting tested, being desperately looking for money and drugs or in need to take drug immediately; they can be under the influence of drugs and not in the condition to give their consent to testing; they are afraid of getting tested because they have engaged in risk behaviours; they want to avoid presence on the street because of fear from police.

To cope with these problems, a solution can be the use of rewards and incentives such as phone cards, food or food tickets, etc.. As experienced in Turin, Bratislava and Prague, giving incentives to clients has been a useful tool to increase their motivation and willingness to get tested, as it was important to have certain sample size within limited time of the study. Even the simple provision of a cup of coffee/tea and some biscuits, as did the social workers in Rome, helped to approach people and motivate them to dedicate some time to their own health.

Outreach units in Rome

Moreover, it is recommended to increase the spreading of information about testing among the target group, distributing informative material or writing dedicated articles on magazines or newsletter distributed in the low-threshold services.

"We have carried out different PR activities towards clients – e.g.: articles in the monthly magazine INTOXI" (Odyseus).

Pre- and post-counselling for HIV and TB

According to CDC, HIV prevention counselling and information is still recommended in all settings, including non-medical services, for persons at high risk for HIV[2].

On the other hand, WHO recognizes that in some settings providing pre-test information, rather than more extensive pre-test counselling (including HIV prevention counselling) may be justified in order to make pro-actively offering HTC feasible[3].

This makes clear that HIV counselling encompasses two components: provision of information and prevention counselling. Despite the setting where the testing is provided, all clients should receive information about HIV testing (clinical benefits and potential risks), HIV infection (way of transmission and prevention), meaning of test results (services available in case of either a negative or a reactive test result, confidentiality and respect of privacy in the treatment of test results).

Providers must also inform clients that they have the right to decline the test and that if the test result is reactive, disclosure to contacts who may be at risk will be encouraged.

In case of HIV rapid test provided in non-medical settings, it's important to give clients a clear explanation of the test procedure and test results. The counsellor should explain that the rapid test has the same specificity and sensitivity of other analysis on whole blood, and as in other type of tests there is the possibility of having false positive; therefore, any HIV-reactive result must be confirmed by other tests.

On the other side, if the client has had risk behaviours in the last three months and the test result is negative, it is fundamental to recommend a re-testing since the period between the infection and production of antibodies is asymptomatic and lasts on an average for 2 to 12 weeks (so called "window period").

However, safer drug use and safer sex behaviours should be always stressed, no matter what the result is.

Prevention counselling is intended as a more interactive process of assessing risks, recognizing specific behaviours that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce these risks. In HIV prevention counselling, the counsellor focuses on assessing the client's personal risks or circumstances and helping him/her to set and reach a specific, realistic, risk-reduction goal.

According to CDC Guidelines, "prevention counselling is a risk-reduction process that might involve only one or more than one sessions"[4].

Traditionally, in the pre-test counselling the focus is on risk assessment, in order to make the person aware of the risks he/she could have encountered and the eventuality of having a reactive result; while the set up of strategies for risk reduction is done in the post-test counselling, when providing the client with test results.

When offering HIV counselling to drug users, it's important to focus on drug-related risk behaviours, encouraging clients to identify the drug use behaviours that put them at increased risk for acquiring HIV and understand the reasons why they continue to engage in them. The counsellor should also explores previous attempts to reduce these risks and support clients in their successes and efforts.

In addition, when providing HIV counselling and testing to socially marginalized groups such as drug users and migrants, it is fundamental to make the clients aware of the legal regulations related to HIV disclosure in respective countries and the potential risks of knowing his own HIV status (e.g.: as discrimination, abandonment or violence).

For example, in Slovakia it is mandatory to disclose the HIV status to health care workers in case that the contact with blood is required (like in dentistry, surgery, etc.), otherwise the person can be prosecuted under the criminal code. However, the disclosure of HIV status very often results in denying the services to the person.

Regarding the pre-counselling on TB, our experience showed that information about this infection is very low, particularly among young people, since it is considered a disease of "the past" and it's not perceived as a current health issue. Therefore, the pre-counselling should focus on the provision of basic information about TB (different forms of TB, difference between latent infection and active disease), as well as on the benefits (clinical and preventive) of early diagnosis of pulmonary TB, treatment possibilities and legal consequences.

At this regard, it's very important to reassure the client that TB is curable, stressing the importance of early diagnosis of tuberculosis as a tool to prevent the worsening of the disease and the spread of the infection to others.

Referring to our specific target group, it is important to explain clients the link between drug use and TB, as well as between TB and HIV, in order to make them acknowledge the risks and understand the reason for the offering of TB testing.

The pre-counselling for TB should be a fundamental step for motivating the target group toward testing and if needed, treatment and care.

Post-test counselling must always be an integral component of the HIV testing process. Everyone undergoing HIV testing must be counselled when their test results are given, regardless of the result[5]. The same applies when TB clinical screening and testing is provided.

Post-test counselling is important both in case of reactive or negative result, because it aims not only to help the client understand and cope with the test result, but also to provide the client with any further information required, and if necessary referring the client to other services.

In case of a HIV-reactive result, it's fundamental to clearly explain that the result has to be considered "preliminary positive" and that there is the need of laboratory confirmation from the whole blood sample to have the definite diagnosis.

However, it is recommended that clients with high-risk behaviours are informed about the probability that the confirmatory test will be positive and receive the necessary support to acknowledge and cope with this information, as it is a very stressful moment.

At this regard, it is desirable that, where possible, the counsellor who provided pre-test counselling also provides post-test counselling. In this

Testing in outreach unit in Bratislava

way, the counsellor has already established a relationship with the client, and can better evaluate the likelihood of a reactive result on the basis of the risk assessment conducted during the pre-counselling.

As for TB, in case of a positive evaluation of the clinical screening, it's important to explain the need for additional testing, such as the sputum examination and X-ray. Only in case of a positive result of these analysis the diagnosis can be confirmed and the client must be provided with detailed information about treatment possibilities and the importance of starting and completing treatment.

Moreover, in presence of any suspected case of TB, it's highly recommended to explain the way of transmission of TB and provide the client with basic information and skills on cough etiquette and how to protect household members from getting infected.

Of course, as already said above, it must be taken into account that the provision of pre- and post-counselling in low-threshold services requires high skills and competencies, to keep up to standards of provision.

In particular, when offering the counselling and testing in mobile street units, the space is limited and most of the clients are in a hurry. Therefore, it's fundamental that the counsellor has adequate capacities and experience, in order to create a confidential atmosphere, understand quickly the specific needs of each client and provide him/her with the most suitable information and support.

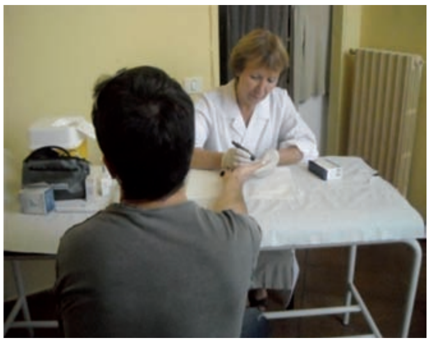
Counsellor has to be also ready to cope with the crisis situation in case of reactive result, to have time to offer client enough safe space for digesting this news. In some cases one session (including pre-test counselling, test and post-test counselling) can take as much as 40 minutes. Sometimes the clients need just time to cry and have chance to step out of the unit without clear marks of the result (not crying, being able to answer questions from other clients, etc.).

> *"We ask clients about their own emotions and thoughts, help them to map their support network (interpersonal and psychological) and ideally create a short-term plan of what will be done in the following hours. If needed, we provide client with aftercare"* (SANANIM).

Conditions for respect of privacy and confidentiality

The study protocol of any testing programme on HIV and TB must necessary foresee a set of conditions that ensure the respect of privacy, confidentiality and security during the all implementation phases. This means that a number of organizational procedures must be followed during the collection, storage, use and disposal of personal identified data and other information.

In line with all international guidelines, the testing should be conducted only after obtaining informed consent of clients. The emphasis on the voluntary nature of the test and the right to decline it, is particularly important when targeting marginalized groups such as drug users and migrants; informed choice is central to create a climate of confidence and trust between the person being tested and the service providers. More-



HIV rapid testing in Turin

Kit for HIV rapid test in Turin

over, it's important to stress that declining the test will not affect the regular access to services.

The informed consent can be given verbally or in writing, depending on the national legislation of each country. In Bratislava, the informed consent was requested verbally in order to respect the anonymity of clients, while in Rome and Turin it was given in writing, but always respecting the anonymity of people tested (no documents or real names were requested).

Moreover, the informed consent, as well as the pre- and post-counselling, should be given individually away from clients or staff not involved in the testing, in order to ensure privacy and confidentiality.

In such kind of programmes, maintaining the confidentiality of client records is critical. Providers should develop written protocols for record keeping that address transport of client records to and from outreach venues and storage in a safe place.

At this regards, it is highly recommended to use codes to identify clients rather than personal names. Within Imp.Ac.T., each client was recorded with a code, reported in the following items:

1) Informative leaflets and informed consent form;
2) HIV rapid test, TB clinical screening form and eventually, container with sputum sample;
3) Questionnaire for data collection and risk assessment;
4) Referral paper for the clinical centre, in case of reactive test result.

Moreover, each client was registered manually on a separate file with a personal code (for example name/nickname and date of birth), according to the coding system normally used by each organization. The combination of these two coding systems has facilitated the identification of all people tested, particularly important in case of follow-up testing and communication of sputum examination results, while ensuring respect of privacy and anonymity.

This was not done in all cities. In case anonymity could not be guaranteed, this was communicated clearly to the clients before they undertake the tests.

All the personal data of people tested under the project have been stored anonymously in a structured online database. The access to data was allowed only to the project staff.

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1 EMCDDA Meeting report "Data-collection at Low-threshold services for Drug Users: Tools, Quality and Coverage", 2004 http://www.emcdda.europa.eu/html.cfm/index5778EN.html.

2 Revised guidelines for HIV Counseling, Testing and Referral (CDC, 2001) http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt_counseling.htm.

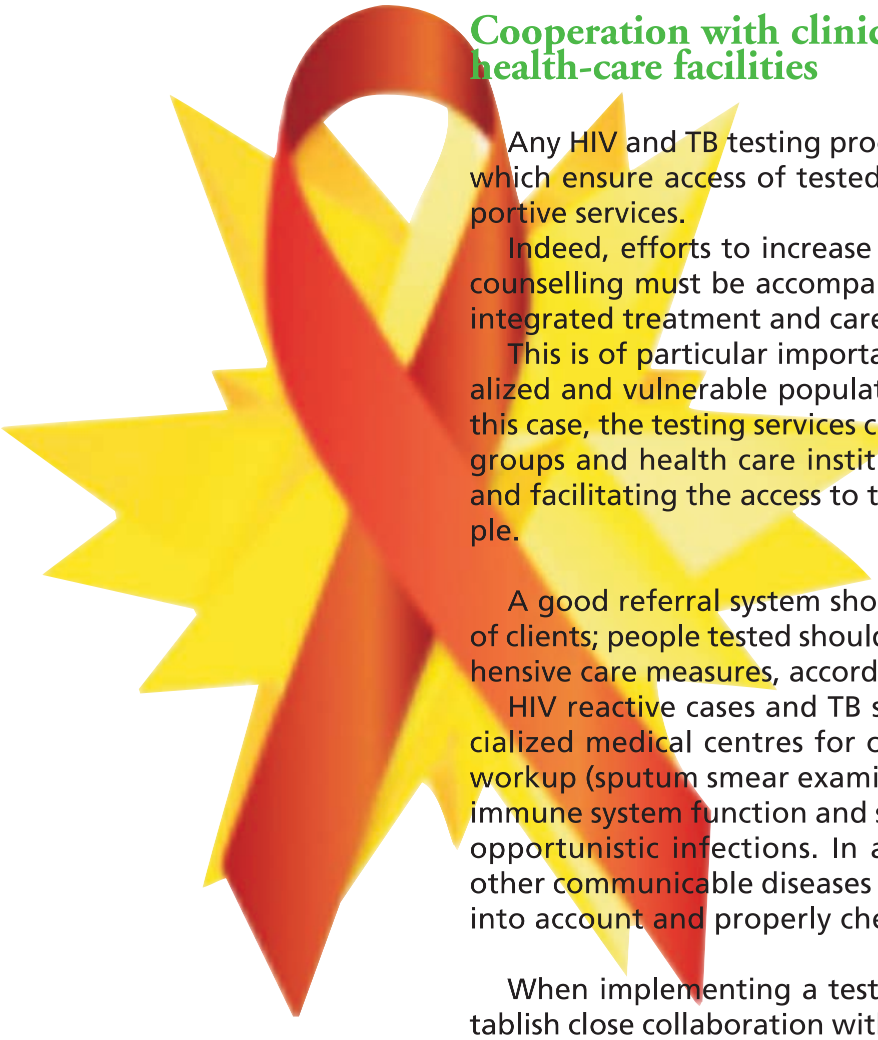
3 Scaling up HIV testing and counseling in the WHO European Region as an essential component of efforts to achieve universal access to HIV prevention, treatment, care and support, Policy framework (WHO, 2010) http://www.who.int/hiv/pub/vct/hiv_testing_counseling/en/index.html.

4 Revised guidelines for HIV Counseling, Testing and Referral (CDC, 2001) http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt_counseling.htm.

5 Scaling up HIV testing and counseling in the WHO European Region as an essential component of efforts to achieve universal access to HIV prevention, treatment, care and support, Policy framework (WHO, 2010) http://www.who.int/hiv/pub/vct/hiv_testing_counseling/en/index.html.

Chapter 4

Follow-up of clients and access to treatment and care for HIV and TB



Cooperation with clinical centres and other health-care facilities

Any HIV and TB testing programme should include a referral system, which ensure access of tested individuals to specialized care and supportive services.

Indeed, efforts to increase access to and uptake of HIV testing and counselling must be accompanied by equal efforts to ensure access to integrated treatment and care for people resulted positive to testing.

This is of particular importance when the target groups are marginalized and vulnerable populations such as drug users and migrants. In this case, the testing services can act as a bridge between hard-to-reach groups and health care institutions, reducing the gap between them and facilitating the access to treatment and care for marginalized people.

A good referral system should take into account the multiple needs of clients; people tested should receive appropriate referral for comprehensive care measures, according to their identified needs.

HIV reactive cases and TB suspected cases must be referred to specialized medical centres for confirmatory test and further diagnostic workup (sputum smear examination, X-ray, blood tests), evaluation of immune system function and screening, treatment and prophylaxis for opportunistic infections. In addition, co-infection with HIV, TB and other communicable diseases (e.g. STDs and hepatitis) should be taken into account and properly checked.

When implementing a testing programme, it is fundamental to establish close collaboration with clinical centres providing HIV and TB diagnosis, treatment and care, in order to set up a referral system to these centres for people undertaking the testing.

Once there is not continuous long-term cooperation, specific agreement (written or verbal) should be made between the low-threshold service providing rapid testing and the medical centres specialized on HIV and TB. These centres should act as the clinical reference centres for all identified suspected cases and should ensure the provision of all required examinations for HIV and TB, as well as treatment and care to those individuals referred there by the low-threshold service.

The agreement should be based on clients needs and on the resources at disposal of the clinical centre. In every collaborating facility there should be a referent person willing to collaborate intensively with the low-threshold service.

In Imp.Ac.T., a collaboration with clinical facilities was set up in each of the four cities. Clinical centres were involved in confirmatory testing and treatment of HIV reactive and/or TB positive drug users. They were also asked to be involved in the development of the testing methodology, in particular for TB. According to consultations with medical doctors from the collaborating clinical centres and other TB experts from the project Advisory board, it was decided to not provide the tuberculin skin test, but instead the clinical screening and the sputum examination or X-ray.

Therefore, it is highly recommend that collaborating clinics (and especially experts on TB) are involved in the project development as well, on a structural basis.

According to our experience, resistance of health facilities toward signing written agreements is often faced, due to bureaucratic reasons or to mistrust of the work of non-governmental organizations. In these cases, it is recommended to refer to institutions that know the activity of the organization and have already collaborated in other projects, or to count on personal contacts between the medical staff of the low-threshold service and the health facilities.

Even in case of informal agreement, the procedure of referral should be clearly defined in the overall study protocol and followed by all the involved clinical centres.

Within Imp.Ac.T., the client referred to the clinical centre was given a “referral paper” indicating the date of HIV rapid test provision and the preliminary test result.

Moreover, in Rome the referral paper included also a summary of the risk assessment conducted during the counselling, with the aim to provide the medical staff with additional useful information about the client.

The referral paper reported the same client’s code recorded in the informed consent form, the questionnaire and the HIV/TB test, in order to allow the identification of the patient while respecting privacy and anonymity.

The good cooperation with clinical centres is very important to facilitate initial contact between drug users and health facilities. In many cases, it is necessary to provide clients with assistance in accessing services, such as setting up appointments and offering accompaniment or transportation. The appointment can be scheduled by the staff of low-threshold services according to the working hours and availability of the clinical centres. At this regard, having a referent person in the clinical centres who can assist in the schedule of appointments is highly advisable and would allow the referral system working smoother. At the same time, it is also recommended to have a person in the low-threshold facilities that can accompany drug users to the clinic and assist in setting up good contact with medical doctors.

In addition, the establishment of good collaboration with low-threshold services may bring health service providers to change their attitudes toward marginalized populations and modify the rules of access to services, adapting them to the specific situations and condition of such people.

As experienced by SANANIM, *"the TB clinic modified the entry criteria: now it is not required an ID card and health insurance company card".*

The set up of a referral system with clinical centres is useful also for the exchange of data between the service providing testing and the clinical centres providing diagnosis and treatment. The exchange of information should be regular and constant and will serve to monitor the number of confirmed positive cases and the number of people entering into treatment after the testing. At this aim, the clinical centres should record the persons referred there by the testing service using the code indicated in the referral paper. This will ensure the exchange of data respecting the privacy and anonymity of clients and according to the international legislation on data protection.

The information to be exchanged between clinical centres and testing services should include not only the number of confirmed diagnosis for HIV and/or TB and the number of people entering into treatment, but also the number of early infections (person infected in the last 6 months) identified through the Avidity test.

Avidity is a measure of the strength of the binding between immunoglobulin G antibodies and the corresponding antigen, a property that increases over a period of months in newly acquired infections. HIV antibody avidity testing provides a reliable method for identifying recently acquired HIV-1 infection.

This information is important for monitoring the dynamics of the epidemic and transmission networks, and it can serve to develop more specific public health intervention programs.

Within Imp.Ac.T., referral to follow up testing and/or treatment worked very well in some cities, but not everywhere. The level of collaboration was not as high as intended. In Rome, the clinic provided follow up and avidity testing data to the project partner, but in other cities this was not done. Even though a good collaboration was achieved in most cities, the communication regarding clients and data could be improved.

Besides clinical centres for HIV and TB diagnosis and treatment, it is important to establish a good cooperation also with other health-care facilities. Drug users have multiple needs that can be addressed through referral to other supporting services, such as STI treatment, opiates substitution therapy, night shelters, employment agencies, legal services, child care, etc.

Addressing these needs can help clients access and accept medical services and adopt and maintain safer health behaviours.

Motivation of clients toward treatment and care

Motivation is an important first step toward any action or change in behaviour. People generally will not perform desired behaviours unless or until they are motivated to do so.

As already said in the previous chapter, motivating drug users towards testing, treatment and care is not so easy and requires specific efforts.

Within Imp.Ac.T., the approaches used for motivating clients to access treatment and care have acted both on external and internal motivation.

External motivation refers to the offering to clients of incentives or rewards, such as food vouchers in Prague and Bratislava, and phone cards in Turin.

Internal motivation implies the use of methods such as counselling and motivational interviewing, which aim at strengthening the client's intrinsic motivation for change.

This approach assumes that drug users are responsible for changing their own behaviours and is designed to support them to reflect upon their own situation and move toward positive behavioural changes. Clients of low-threshold services are usually in the phase of 'negation' (not only of health risks); therefore, it is crucial for the workers to confront drug users with health issues and discuss their responsibility toward themselves and others.

For the majority of people, the disclosure of his/her own HIV positive status represents a stressful moment and for somebody it can be a real shock. In these cases, people are not ready to cope with this new information and think clearly about what they need to do.

Therefore, the service providers should have the capacity to understand this feeling and establish a relation of confidence and trust that support and encourage clients toward personal responsibility.

According to what experienced during the project Imp.Ac.T., in many cases drug users require time to get the necessary motivation toward treatment and care. So, it is important to offer constant support and counselling, stressing the benefits of early access into treatment and care for themselves and their environment.

> *"To motivate some of the clients resulted HIV "preliminary positive" to go to the clinical centre for confirmatory testing and treatment, we had to talk with them several times, encouraging them to do it any time they came to our services"* (Villa Maraini).

For those clients who don't have any contact with health services and have some resistance toward referring to medical centres, it can be very useful to offer a practical assistance such as the schedule of appointment, accompaniment or transportation to the clinical centre. If people are offered to be accompanied by a worker of the low-threshold services, they accept more easily to go to clinics for confirmatory testing.

One of the main problems encountered within Imp.Ac.T. has been the low motivation of clients toward TB diagnosis. The majority of clients identified as suspected cases and requested to give a sputum sample for examination, didn't come back for taking the results and giving a second sample. In Prague, a high percentage of clients with "positive" TB clinical screening didn't go to TB clinic for further diagnostic check-up, as indicated. The reason is that drug users don't perceive TB as a major health problem and have very low information about this infection. Therefore, they do not consider the possibility of being infected and don't care about the need of medical examination.

As reported by SANANIM, *"DUs are not afraid of TB; clients have no direct experience with TB, because of low prevalence of TB in Czech Republic".*

Conditions for ensuring follow up of clients

Health-care service providers should work to remove barriers to accessing services and make them responsive to client needs and priorities.

In fact, one of the condition for ensuring access to and adherence to treatment and care is that clients find services accessible and acceptable. Research has indicated that referrals are more likely to be completed if services are easily accessible and tailored to client specific needs.

When talking about public health services, this can require a modification of working rules and procedures, such as the extension of opening hours, the schedule of appointments and provision of test results in a shorter time, and so on.

In consultation with clients, the service providers should assess and address any factors that make the follow-up difficult (e.g., lack of transportation or child care, work schedule, cost), and assist the clients to find a solution for these problems.

As already said above, many clients resulted "preliminary positive" to testing within Imp.Ac.T. have been accompanied to the clinical centres by the workers of the low-threshold services, and this solution has contributed to increase the motivation of clients toward referral.

However, besides the motivation, it is important to ensure that the clients do not encounter any barrier in the access to clinical centre.

As reported by Villa Maraini, *"a clinical centre gave the appointment for the confirmatory testing after one week, and after a month for the testing results. This can represent a problem for our clients".*

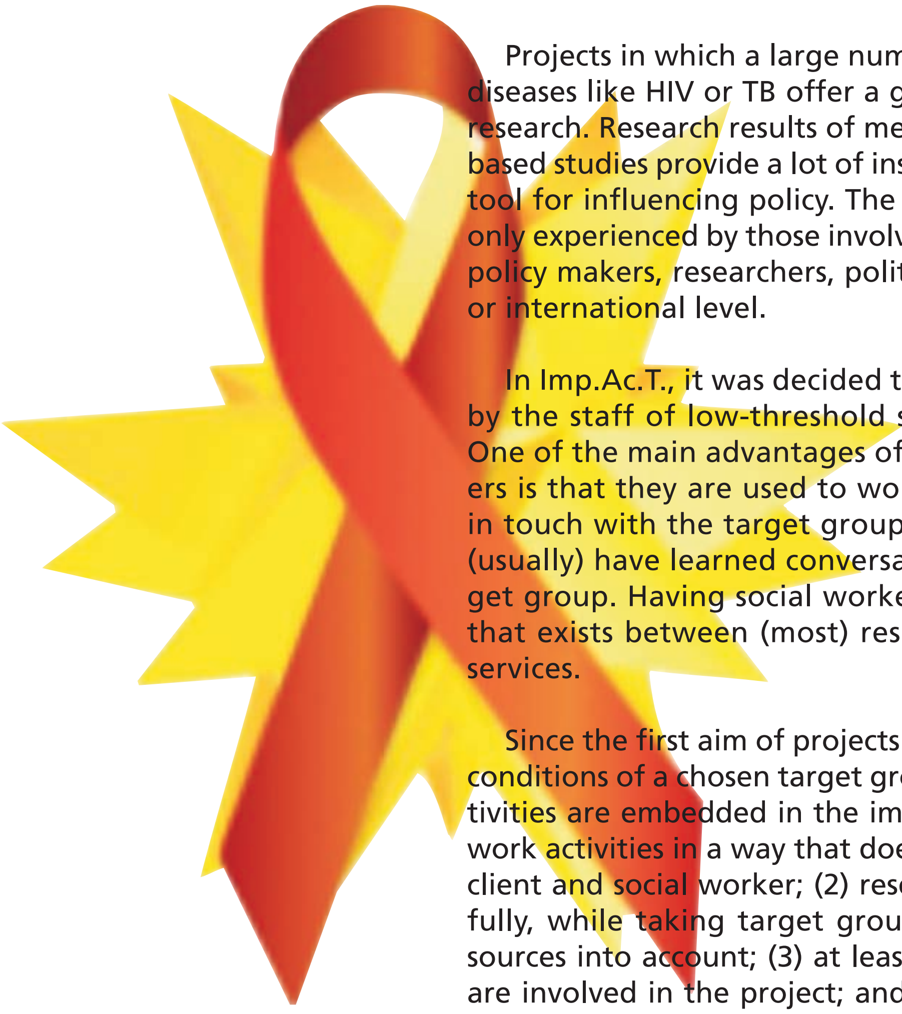
In addition to this, it is important to take into account that some clients can have difficult living conditions which make problematic the follow-up and adherence to treatment. For example, they can be homeless or without a stable accommodation, can be arrested and sent in prison for some time, can move to other places far from the referred clinical centre.

At this regard, it is highly advisable to make an assessment of client's needs and constraints and offer support and assistance through referral to appropriate social and health-care facilities.

Of course, it is recommended to refer clients to services close to the one providing the testing, in order to facilitate their monitoring and follow-up.

Chapter 5
Data collection and analysis

Introduction



Projects in which a large number of people are tested for infectious diseases like HIV or TB offer a great possibility for data collection and research. Research results of methodologically sound implementation-based studies provide a lot of insightful knowledge and can be a strong tool for influencing policy. The impact of these kind of projects is not only experienced by those involved directly, but can also be shared with policy makers, researchers, politicians and other parties; on a national or international level.

In Imp.Ac.T., it was decided that the data collection would be done by the staff of low-threshold services of the partner organisations. One of the main advantages of involving social workers as interviewers is that they are used to working with the target group. They are in touch with the target group, even hard-to-reach clients, and they (usually) have learned conversation skills that are tailored to the target group. Having social workers as interviewers can bridge the gap that exists between (most) researchers and clients of low threshold services.

Since the first aim of projects like this is usually to improve the living conditions of a chosen target group, it is important that (1) research activities are embedded in the implementation and in the normal social work activities in a way that does not disturb the relationship between client and social worker; (2) research methods have been chosen carefully, while taking target group, available knowledge, skills and resources into account; (3) at least one and preferably more researchers are involved in the project; and (4) adequate channels to disseminate results to a wider public are available. Furthermore, it is also highly recommended to (5) involve social workers, outreach workers, as well as representatives of the target group in the development of research tools, if they are going to do (part of) the data collection.

Use of a questionnaire to systematically collect data

Two questionnaires were developed within Imp.Ac.T. The first one was the main questionnaire which was administered the first time a participant was tested. The second one was a follow up questionnaire which was administered whenever participants came back for follow up testing (after at least 3 months after HIV testing with a negative result, or whenever TB symptoms were present).

In terms of content of the questionnaires, most of our items were in line with the Drug Related Infectious Diseases key indicator (Standard Table 9) of the EMCDDA[1].

For the format of the questionnaire, examples were used of a questionnaire of the RIVM and Spallanzani[2].

The questionnaire was adapted and shortened multiple times after reviewing it with the implementing partners and with members of the advisory board[3]. Afterwards, the questionnaire was piloted with 44 pilot participants (target group members).

The main questionnaire consisted of 9 sections (see Box 1). Routing logic was developed in a way that questions that were not applicable could be skipped. For instance, if a participant would answer the question "Have you injected drugs in the last 4 weeks?" affirmatively, the following 2 questions regarding injecting drug use "in the last 12 months" and "ever" could be skipped.

Box 1 - SECTIONS AND VARIABLES OF THE MAIN QUESTIONNAIRE

A. ***Recruitment:*** *date of interview, place of recruitment, city of implementation.*
B. ***Social Demography:*** *gender/sex, year/month of birth, housing situation, homelessness, migrant status, level of education, work situation.*
C. ***Drugs:*** *onset of drug use, injecting drug use (last 4 weeks, last 12 months, ever), drug use last 4 weeks (which drugs), IDU last 4 weeks (which drugs), needle sharing (last 4 weeks, last 12 months, ever), reason to share needles, sharing cotton, wool, filter, spoon, flushing water or other items (last 4 weeks, ever).*
D. ***Prison:*** *Imprisonment ever, nr of times in prison since onset drug use, IDU in prison, number of people in cell last time.*
E. ***Sexual partners:*** *sexual intercourse last 12 months, with (1) stable partner, (2) casual partners, (3) sex workers, or (4) as a sex worker, number of partners, condom use with each of these type of partners, IDU of stable and casual partners, diagnosis of STD.*
F. ***HIV testing:*** *ever tested before, ever offered test before, reasons not to be tested, reasons to take test now.*
G. ***TB testing:*** *TB vaccinated, ever tested before (which test), ever offered test before, reasons not to be tested, reasons to take test now.*
H. ***Remarks participant***
I. ***Remarks interviewer***

Based on experiences in the piloting of the questionnaire, it was decided to make some minor textual changes to the questionnaire and add an extra introduction to the section on sexual behaviour. In this introduction participants were made aware of the explicit and private nature of the questions, they were told why these questions were necessary, and confidentiality was again emphasized. Participants were again told that they had the right to refuse to answer questions. Finally, it was explained that all questions concerned the last 12 months and that sexual intercourse meant vaginal or anal intercourse only.

Administration of questionnaire in Turin

In the piloting of the questionnaire, it was measured how much time the administration of the questionnaire took. Questionnaire administration time varied from 8 to 17.7 minutes (mean 14.6 minutes). After the pilot, the section with questions regarding sexual behaviour was still considered too long and sometimes intrusive in two of the four cities; whereas in the other two cities it was not considered too long or intrusive. This could be related to local characteristics of the target group (sex workers might respond differently to these kind of questions than older alcoholic homeless people) and/or the attitudes or culture within local service providers.

The follow up questionnaire consisted of the same 9 sections that are mentioned in Box 1, but was slightly different in content and question formulation. A lot of the demographic questions did not need to be repeated in the follow up. Risk behaviours were measured either “since the last interview” or only “last 4 weeks”, so that changes in behaviour compared to the first interview could be measured. In the sections for HIV and TB testing questions were added regarding intentions to get tested in the future (“would you go to the clinic for follow up testing?”, “why not?”) and perceived risk behaviour change since the last interview.

Database

Since a large number of data would be collected and entering paper data into excel or SPSS would take a lot of time, it was decided to make use of an online database. The project leading organisation developed a database which could be entered by all the partners from the project website. This database was a system in which questionnaire data could be entered one by one. There was no routing logic[4] in this questionnaire, and each answer had to be filled in by mouse click or open entry. Three out of four partner organisations filled out the questionnaires on paper after which the data were entered in the online database. For these organisations it was not possible to use a laptop with internet during the questionnaire administration, so they could not make use of an online survey tool.

One partner organisation wanted to make use of an online survey tool with direct data-entry, since they had the possibility to use a computer with internet connection during the interview administration. When using an online survey tool, the questionnaire is not administered “paper-and-pencil” but computer-assisted, and data are entered into a database immediately on the spot.

Since the project database had some disadvantages in terms of direct data entry (no routing logic, questions in English), this partner organisation developed its own online application using a free open source program called LimeSurvey, under supervision of the researcher. We experienced that this survey tool had a number of advantages over the other database (see Box 2); however, it should be noted that using an online survey tool is not always possible or preferred, especially not when collecting data “on the streets”.

Box 2 - USING AN ONLINE SURVEY TOOL: ADVANTAGES AND DISADVANTAGES

- *Time saving: data are immediately entered into the database while they are being collected, therefore they do not need to be entered again after the interview.*
- *Mistake-resistant and limited missing values: no questions can be left unanswered, only those questions that are relevant are asked (routing logic determines which question is the next), no data-loss or mistakes in between questionnaire administration and data entry.*
- *User friendly: Routing logic determines which question should be answered next, therefore the interviewer does not have to check the routing while doing the interview, and can focus more on the participant.*
- *Developing the online survey can lead to more involvement with the data collection; thereby increasing commitment and responsibility of the partner organisations.*
- *Provides an opportunity to become familiar with building a data monitoring system for other purposes (the partner organisation is still using this system for monitoring other data).*
- *Computer-assisted interviewing requires a computer with working internet connection (and table and chairs), which is not always possible in outreach work.*
- *Creating the online survey in a program (limesurvey, surveymonkey, NetQuestionnaires, etc.) requires some time and dedication of someone willing to learn programming online surveys in the development phase of the project. Most of these programs are easy to use though, and do not require specific programming or technical skills.*

Apart from the questionnaire, also test results were entered into both databases (see Box 3). All data could be exported to SPSS. The two databases were merged on the basis of unique respondent codes, which consisted of 2 letters (city code) and 4 numbers (an extra “O” was added for Out-of-target-group cases).

Box 3 - TEST RESULTS SECTION

HIV rapid test successful (yes or no)
HIV rapid test result (reactive, negative, invalid)
Confirmatory HIV test result (reactive, negative)
Presentation for HIV treatment (date)
Avidity test results (early or late infection, and date)
TB risk assessment result (negative or positive)
Sputum 1 and 2 collected (yes or no, and date)
Result sputum 1 and 2 (negative or positive, and date)
Confirmatory TB test results (negative or positive, and date)

Response Monitoring Form

People who want to participate and people who do not want to participate in these kind of projects might constitute different groups, for example in terms of demography. These differences might be related to self-selection, or possibly selection from the person doing the recruitment. To be able to do a response analysis in which so-called "responders" are compared to "non-responders", a response monitoring form (RMF) was used. On the RMF, a few details of every person who was approached for the testing were recorded: (1) gender, (2) country of origin, (3) age, (4) eligibility for the project, (5) eligibility for HIV testing (for TB, people were always eligible to get screened), (6), willingness to participate, and (7) if not willing, reason not to participate.

The RMF was not only used as a method to monitor response, but also as a recording aid for the eligibility check. Indeed, the selection and recruitment of clients for testing was done according to clear inclusion and exclusion criteria, identified during the development of the study protocol (see Box 4).

Box 4

INCLUSION CRITERIA

- *Problem Drug Users, i.e. injecting drug user or with a long duration/regular use of opioids, cocaine and/or amphetamines.*
- *Clients of low-threshold facilities for DUs (drop-in centres, night shelters, outreach/street units, centre for substitution therapy.*
- *Being over 18 years of age.*
- *Able to understand the purpose and procedures of the testing.*
- *Able to give their informed consent (written or oral).*

EXCLUSION CRITERIA

- *Being under 18 years of age.*
- *Not understanding the study's purpose and procedures and therefore unable to give informed consent (because under the effects of drugs or for language barriers).*
- *Being tested for HIV in the last three months.*
- *HIV positive (only for HIV test).*

The definition of the target group was important from a research point of view, since it allowed to define the sample size and characteristics. However, during the carrying out of testing, the selection of clients on the basis of eligibility criteria raised some problems and ethical issues, since it implied the exclusion of a consistent number of people attending the low-threshold services (alcohol users, occasional drug users, sex workers). Therefore, during the implementation phase it was decided to enlarge the testing to all the clients of the involved facilities, but maintaining "problem drug users" as the main sample of the study/research.


Response Monitoring Form in Bratislava

The experiences with response monitoring were divided. Most partners agreed that it was a lot of work and that it interfered with the "normal" social work/ outreach work activities. Also the copying of the RMF details into an excel sheet, was demanding and created a lot of extra workload. Future projects aiming to do a similar intervention are advised to carefully weigh the pros and cons of using response monitoring in their research, as it might be counterproductive in terms of support of the research element of the project.

Combining data collection with intervention: "role switching"

In Imp.Ac.T., it was decided to combine the questionnaire with the testing and the counselling into one single session. After informing participants, receiving informed consent and pre-test counselling, the HIV rapid test was administered and the TB screening (including testing if necessary) was done. The questionnaire was either administered before the test, or in the waiting time (approximately 15 minutes) for the HIV rapid test result. After the questionnaire, the test results were given and post-test counselling was done.

Combining research activities with testing, counselling and "regular" social work requires specific skills and effort of the people responsible for the data collection. In the case of Imp.Ac.T., social and outreach workers, psychologists/counsellors, doctors and nurses were responsible for the recruitment, counselling, testing and interviewing (data collection). The workers needed to switch from their usual role to their role as Imp.Ac.T. "recruiter", counsellor, and interviewer. For example, motivating people to enrol in the project or dealing with the emotional situation after receiving positive test results, required different skills and attitudes compared to administering the questionnaire. It can be difficult for social workers to do the interviews, as certain questions would not be asked in a counselling session or regular client contact.Some questions might be experienced as "unnatural" to ask because the social workers already know the answer.

Others might be experienced as rude because they would never ask the question in regular client contact. On the other hand, talking about delicate issues like risk behaviours in the counselling, could also enhance the relationship between social worker and client, and this has been reported by at least one of the partners.

In Imp.Ac.T. we tried to ease the transition between roles in two ways. First, workers were trained on how to provide a clear instruction to the participant before the questionnaire (see Box 5). Second, the changing of roles was addressed in the training sessions, where workers had to practice using the instruction and the questionnaire.

Box 5 - INTRODUCTION TO THE QUESTIONNAIRE

"When I start asking you the questions, I am an interviewer and not the social worker/ nurse anymore. I have a different role than usually. This means:

- *That I will ask the questions as if I don't know anything about you.*
- *That the things that you tell me here, will not be recorded in any file of the service, and will remain within these four walls (figuratively speaking). Everything you say is totally confidential.*
- *That some of the questions are quite formal, long, and not "the way we usually communicate". It is important that I ask the questions the same*

to everyone, as they are formulated on paper here. If you do not understand the question, please indicate this to me.

- *That some answers require a simple yes or no, and others are more open questions. However, there is not really time to discuss things, it is a structured interview. But if you have questions or want to discuss things further, we can discuss this after the interview.*
- *Last but not least: there are no good or bad answers. Please be honest in answering the questions."*

Despite the above mentioned preventive measures, the switching of roles between social worker and interviewer was sometimes experienced as problematic. More specifically, in one of the four cities, the role switching was perceived as a "role conflict" between research and social work. This conflict is described here, as well as lessons to be learned.

For the social worker, to listen and help clients is the most important and most rewarding aspect of his or her work. Tasks like providing basic needs, counselling, medication, company, will always come before filling in a form, preparing a report, or administration of a questionnaire; even though the social worker knows that research could ultimately improve the situation of the client in a more structural way.

For the researcher involved in these kind of projects, to "help" these clients of low threshold services is also a strong motivation for his work, but on a different level: to collect information that is useful in order to get a clear picture of these target groups on a wider scale (for instance, European), and ultimately, to improve the situation, if needed.

The social worker and the researcher have the same goal, but different perspectives. Their work demands different roles but are each valuable in their own way. The different perspectives can be polarized on scales, for example; (1) helping individuals directly on the spot, versus helping larger groups of people, maybe, in the future; (2) providing help versus asking for participation; (3) showing empathy versus being more neutral/distant; (4) trying to get people in the project that need it most, versus random recruitment; and (5) trying not to reopen old wounds with those who have already suffered, versus getting as much information as possible, also on sensitive issues.

When these differences are overemphasized and gaps are not bridged, this could lead to resistance or mistrust regarding the data collection among social workers. This could be counterproductive, possibly leading to lack of attention, omissions or mistakes. This is a risk that should not be underestimated. Adherence and compliance to research protocols can be reached only if the alliance between researchers and social workers is firm and both parties are convinced of the usefulness of the tools used and benefits that will come from them. Furthermore, the social workers have to be prepared to take up a role that is normally not part of their work. They made a choice to be a social worker, not to be involved in research; however within programmes like this, the social workers are the supporting pillars of the data collection. This should be acknowledged, discussed, and rewarded.

After signalling the problems with the role switching in one city, specific actions were taken. First, it was decided to do extra focus groups with staff members, to identify possible problems in the project implementation and develop extra training to deal with these. Role playing was used to train the interviewers further. Furthermore, the interviewers were called to an additional meeting to discuss the conflicting roles (social worker versus interviewer).

For future projects, a number of considerations should be taken into account with regard to role switching (see Box 6).

On the one hand, the social workers/ outreach workers are experts in terms of possibilities and limitations in the daily practice of working with the target group. On the other hand, research activities usually require following a fairly rigid protocol, which is not always easy; therefore it is crucial that the people involved with data collection are supporting it.

Box 6 - ROLE SWITCHING - LESSONS TO BE LEARNED

- *Be fully aware of the fact that social workers cannot "turn off" their knowledge of their clients and do not want to jeopardize their relationship of trust with these clients. In the case of collecting of highly sensitive data, it could be difficult and would need specific attention.*
- *Acknowledge the fact that social workers are experts in terms of possibilities and limitations in the daily practice of working with the target group. In order to achieve involvement and compliance with the research protocol from the workers, they need to support the research protocol, but also feel supported by the project management and involved researchers.*
- *When developing the indicators, it is advisable to involve social workers, target group representatives and researchers, so that feasibility of the methods in practice is clear at the outset of the project.*
- *For each location, it could be helpful to set up an alliance between a social worker/ local project leader and a researcher, who are both responsible for the implementation and the data collection at the site.*
- *Training of staff should preferably be done by one of the main researchers, first-hand, not second-hand; preferably together with a social worker, and include multiple role playing sessions.*
- *After the pilot phase, the data collection should be monitored regularly by the researcher. It is important that not only the actual database entry is monitored, but also the experiences of the interviewers with the data collection.*
- *In case of problems with conflicting roles, have extra focus groups among the interviewers, so that problems will become clearly defined, and actions can be chosen.*
- *The culture within organizations seems an important factor in how research activities are perceived and fulfilled. In some organizations, a (slightly) negative attitude towards research exists, based on earlier experiences, expectancies regarding involvement of the government, or other ideas regarding data collection and privacy. It is important that this is addressed; that actions are taken to "boost" the image of research activities; and that negative reactions are curbed.*

- *Use experiences of interviewers to improve the data collection tools (shorten questionnaires, adapt wording, etc), if possible.*
- *It seems a good idea to show to the social workers how much their work for the data collection is appreciated, as this may also enlarge their involvement. They usually do not receive extra credit or salary for it, even though the work requires a different mindset and extra effort. A reward in the form of a gift, social event, or other expression of appreciation could be helpful in order to increase support.*

Use of pre- and post-intervention focus groups

Why focus groups?

Within Imp.Ac.T., a qualitative pre- and post-intervention measurement – in the form of focus groups – was chosen as the most appropriate method to show behavioural change and changes in experiences. Quantitative methods could not reveal all the possible barriers and bottlenecks in the implementation in an accurate manner, since it was unlikely that all possible problems would be foreseen and captured in questions at the outset of the project.

Focus group interviewing is particularly suitable for gaining insight into people's shared understandings of a specific subject, exploring people's knowledge and experience by using group interaction. It can be used to examine not only what people think, but also how they think and why they think that way[5].

In Imp.Ac.T., focus groups could provide a lot of relatively detailed information on the knowledge about TB/HIV and attitudes toward testing and treatment, both before and after the project. The focus group data could give more depth to the questionnaire data regarding HIV and TB testing. Furthermore, one of the focus groups was used to evaluate the project by participants.

What is a focus group?

A focus group is a group of individuals selected and assembled by researchers to discuss and comment on, from personal experience, the topic that is the subject of the research[6]. Focus groups are not the same as a group interview; the interaction between the participants is what distinguishes focus groups from group interviews. Group processes can help people explore and clarify their views, in their own vocabulary[7]. A focus group usually consists of six to ten people who are selected to meet together and discuss their views and ideas on one or two topics. A facilitator, or moderator, leads the group and guides the discussion. This is a task that should not be underestimated. It requires good preparation and a complex set of skills, since the level and quality of the moderation will affect the quality of the interaction between participants[8]. An assistant-moderator or observer may observe non-verbal signals, keep track of time, record the discussion, listen actively if topics are covered enough or if the level of the discussion should be deepened. The observer can also make or assist with making the focus group report, based on the transcript of the recorded discussion.

Limitations and benefits

It is important to remember that the data of a focus group can lack the depth of the information from an individual interview, but the information may be broader in content and can be elaborated on with others. The moderator has less control over the data produced than in one-to-one interviews or quantitative studies[9]. Also, it should not be assumed that the individuals in a focus group are always expressing their own views; they might be expressing the “group view”, they are speaking in a specific context, within a specific culture. An important benefit of focus groups is that they can provide the opportunity for target group members to be valued as experts, to be given the chance to work together with researchers, which can be empowering to many participants.

Training and focus group manual

In Imp.Ac.T., social workers were trained to moderate and observe the focus groups, thereby increasing their expertise and skills and involving them in the research. All partners in Imp.Ac.T. had already gained experience with the use of focus groups before. A training session of half a day was organized by Gruppo Abele for all moderators in one of the project meetings. A short manual was developed which consisted of a list of preparatory activities, the sampling strategy (selection of participants), the topic list, instructions for discussion moderation, debriefing/ education session, and the reporting format. Some general rules for the moderation of the discussion are mentioned in Box 7. Note however that this is not a full list of instructions for focus group moderation. For more information on focus group moderation, see for example Cronin (2008).

Box 7 - SOME INSTRUCTIONS FOR FOCUS GROUP MODERATION IN IMP.AC.T. PROJECT

1. *Main topics are introduced with OPEN questions. Do not introduce the questions or elaborate on them, because you might guide the participants that way. Keep it short and don’t explain or provide examples like “for instance, what kind of symptoms…”.*
2. *Subtopics are only introduced if they don’t come up in the discussion. Wait with posing subquestions until after approximately 10-15 minutes of discussion.*
3. *Make sure that you do not talk about Imp.Ac.T. before the discussion has ended. The participants should not know anything about Imp.Ac.T. until the discussion has ended. This is crucial!*
4. *Do not provide information yourself within the focus group session. There will be a short education session at the end of the focus group.*
5. *Avoid interpreting the participants directly: “so, actually you are saying that…”. Don’t do this, you are steering the participant this way.*
6. *When closing a topic or subtopic, summarize in a few sentences what has been said, and ask if you have understood it correctly. Then introduce the new topic.*
7. *The observer should make basic notes on a print-out of the reporting format, e.g., non-verbal signals, important remarks or inconsistencies. However, do not make notes of the whole meeting since you will miss the non-verbal signals.*

8. The observer should also take note of what's happening in terms of power dynamics, hypo- and hyper representation of participants, leadership level of participants. Some of the information should be reweight in terms of this.

Topic List

Within Imp.Ac.T., 4 focus groups per implementing city were held, so data from in total 16 focus groups were gathered. The construction of the focus group content as well as the topic lists was done together by all involved partners in one of the project meetings, supervised by the project researcher and evaluator. Two of the four focus groups were held before the implementation, and two after implementation. Focus group 1 was about TB and focus group 2 was about HIV (knowledge of symptoms, transmission, protection; and access to testing and treatment facilities). Focus group 3 was held with participants who did not take part in the project. Knowledge on TB, HIV, Access to TB and HIV testing and treatment, and experienced change in knowledge and access to facilities (since the start of the project) were the main topics of focus group 3. Focus group 4 was held with participants who were tested and interviewed within Imp.Ac.T. The same topics were discussed as in focus group 3, completed with an evaluation of Imp.Ac.T. Target group members could participate in a focus group only once. A summary of the topic list including subtopics, example questions and example follow up questions was provided (and will be available to others). Each focus group ended with a short debriefing and education session.

Reporting

Focus groups were recorded (audio). Participant characteristics were noted (anonymously) by the observer. For practical reasons (constrained time and resources) we could not transcribe every word that had been said in the focus groups. The person who was responsible for writing the report (either the moderator or the observer) was asked to use a standard reporting format. This format required that for each subtopic (1) the most important information was summarized in the participants" vocabulary, in such a way that all expressed views were reported, the level of agreement between participants was clear, without interpretation of the author; (2) personal observations could be added in square brackets; (3) literal quotes were transcribed including the participant characteristics and the timing in the digital recording.

The experiences with the focus groups as well as the reporting on them were largely positive. It was sometimes difficult to find enough participants, especially for the focus group in which people who had not taken part in Imp.Ac.T. were interviewed. Moreover, it was sometimes difficult to remember which clients had been tested within the project and which clients had not, and in some cities, most clients of the facilities had been tested in Imp.Ac.T. Furthermore, at least in one of the cities it was sometimes difficult to moderate focus groups with clients who were under the influence of drugs and/or having (severe) mental health problems. A lesson to be learned is that exclusion criteria for focus group participation might be more clearly defined. Despite these difficulties, all partner organisations had done a good job at collecting the focus group data and the overall experiences were very good.

Data analysis

Data reduction and analysis in these kind of projects should be done by a researcher or someone familiar with statistical methods. In Imp.Ac.T., all quantitative data were cleaned, merged, transformed and analysed using SPSS 18. All syntax was saved so that analyses were replicable. Descriptive analyses were done, and if possible, epidemiological measures were calculated (incidence, odds). When possible and informative, group differences were compared using either Chisquares, T-tests or Analysis of variance (ANOVA). Results were considered statistically significant when $p<0.05$.

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1 Various authors, edited by L.Wiessing (2006). Protocol for the implementation of the EMCDDA key indicator Drug Related Infectious Diseases (DRID), downloaded from the website: www.emcdda.europa.eu/themes/key-indicators/drid.

2 The questionnaire was used within the project "Feasibility of an outreach program of HIV rapid testing among marginalized people living in Rome, Italy, implemented by the National Institute for Infectious diseases "L. Spallanzani" and Fondazione Villa Maraini o.n.l.u.s. in 2010.

3 Dr. Enrico Girardi of L. Spallanzani, Dagmar Hedrich of EMCDDA, and especially Lucas Wiessing of EMCDDA provided a lot of helpful feedback, for which we are very thankful.

4 Routing logic refers to the possibility to skip questions and jump to other questions based on the answers of the respondent.

5 Kitzinger, J. (1995). Introducing focus groups. *British Medical Journal, 311*, 299-302.

6 Powell, R.A., & Single, H.M. (1996). Fucus groups. *International Journal of Quality in Health Care, 8(5),* 499-504.

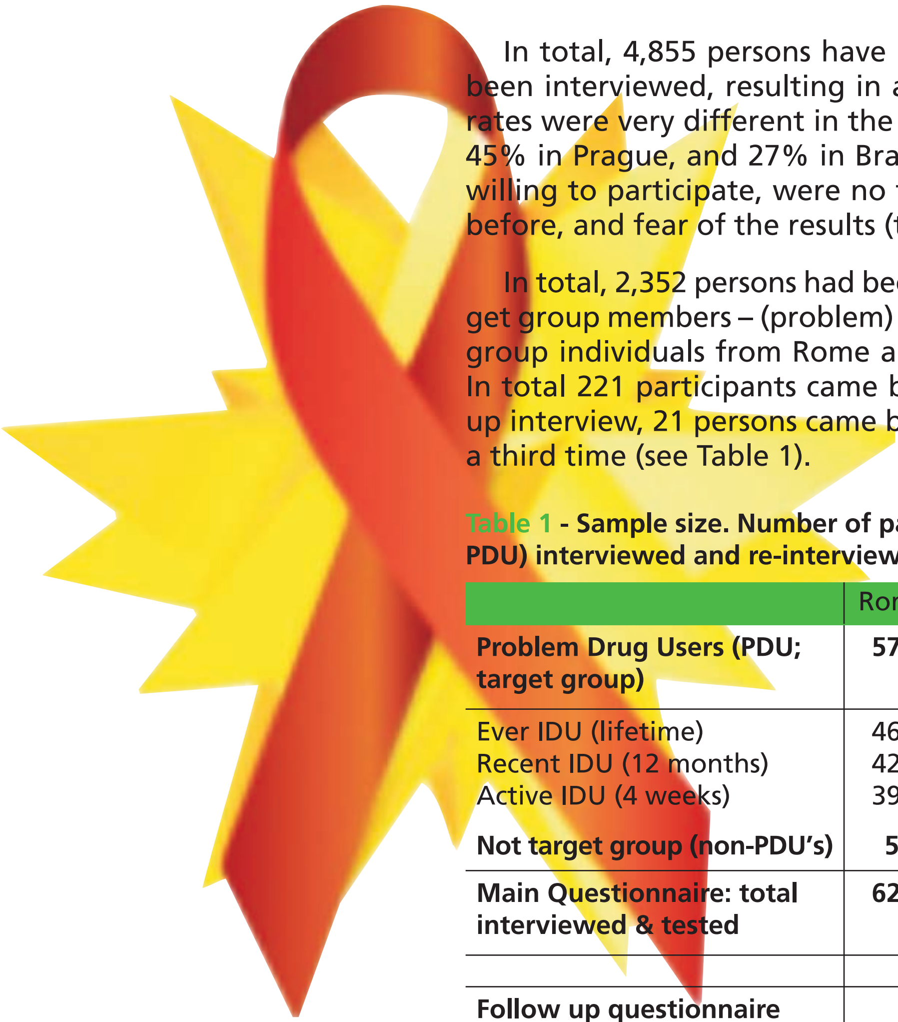
7 Cronin, A. (2008) Focus Groups. In: N. Gilbert (Ed.), *Researching social life*. London: SAGE Publications Ltd.

8 Morgan, D.L. (1988) in: Gibbs, A. (1997). Focus Groups. Social Research Update, 19.

9 Gibbs, A. (1997). Focus Groups. Social Research Update, 19.

Chapter 6
Results

Response



In total, 4,855 persons have been approached, of which 2,352 have been interviewed, resulting in a total response rate of 48%. Response rates were very different in the four cities: 53% in Rome, 75% in Turin, 45% in Prague, and 27% in Bratislava. The main reasons for those not willing to participate, were no time/ in a hurry, no interest, HIV tested before, and fear of the results (to a lesser extent).

In total, 2,352 persons had been interviewed, of which 2,191 were target group members – (problem) drug users – and 157 were out-of-target group individuals from Rome and Bratislava, no (problem) drug users. In total 221 participants came back for follow up testing and a follow up interview, 21 persons came back for a second time, and 1 person for a third time (see Table 1).

Table 1 - **Sample size. Number of participants (PDU, ever IDU, recent IDU, non-PDU) interviewed and re-interviewed (follow up)**

	Rome	Turin	Prague	Bratislava	Total
Problem Drug Users (PDU; target group)	**571**	**570**	**869**	**181**	**2191**
Ever IDU (lifetime)	466	460	844	173	1943
Recent IDU (12 months)	422	417	801	169	1809
Active IDU (4 weeks)	393	325	713	159	1590
Not target group (non-PDU's)	**57**	**0**	**0**	**100**	**157**
Main Questionnaire: total interviewed & tested	**628**	**570**	**869**	**281**	**2352**
Follow up questionnaire (retested participants)					
Follow up 1	25	32	124	40	221
Follow up 2	2	0	9	10	21
Follow up 3	0	0	0	1	1

Quantitative results from the questionnaires

Socio-demographic characteristics

Target group members were significantly younger (mean age = 34.3) than the out-of target group individuals (mean age = 38.7)[1]. Non-target group people were significantly more often homeless (53%) than target group members (43%) and also less often unemployed (55%) than target group members (67%)[2]. So, the out-of target group was slightly older, more often homeless and less often unemployed. This is not unexpected since a large out-of target group of participants in Bratislava were sex workers (therefore not unemployed), and a large part of the out-of-target group participants in Rome were homeless people. Almost 74% of all participants were male. Regarding age, homelessness and migrant status, differences between the four cities were quite large and significant. As far as migrant status, 13 percent of participants were migrants, but this was also quite different between the four cities, ranging from 3% in Bratislava to 25% in Turin. Therefore, it seems not justified to speak of "one target group" as a whole, as the target group seems to be slightly different in each of the four cities. Socio-demographic characteristics of the Imp.Ac.T. participants are displayed in Table 2.

Drug use characteristics

Of the target group participants, 90% had ever injected drugs (82-85% in Italy and 98 % in Czech Republic and Slovakia), 84% had injected drugs in the last 12 months (recent IDU) and 73% had injected drugs in the last 4 weeks (active IDU; 60% in Turin, 69% in Rome, 83% in Prague and 90% in Slovakia), see also Figure 1.

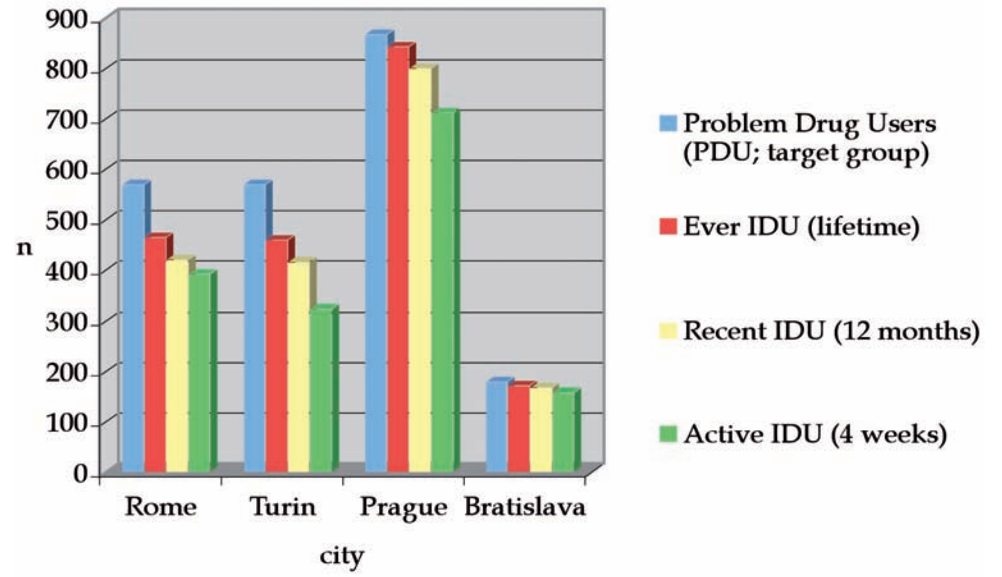


Figure 1
Numer of PUD's; mever, recent and active IDU's

Drug use patterns of active drug use (in the last 4 weeks) were quite different for the four cities. In Rome, heroin was by far the most popular drug (83%) followed by cannabis and cocaine on a shared second place (both 50%) alcohol (31%), and benzodiazepines (18%). Other drug use was low (0 to 5%). In Turin, the pattern of drug use was more diffuse. Cocaine was the most used drug (77%, often injected), followed by one footstep by heroin (72%), then alcohol (33%), methadone (30%), benzodiazepines (26%), and cannabis (24%); use of other drugs was low (0 to 5%). The difference between Rome and Turin in drug use might be partly related to higher methadone use in Turin, which could explain the low use of heroin. In Prague, heroin use was the lowest, only 15%. However, a lot of other drugs were used in Prague, with pervitin (metamphetamines) as the most used drug (78%), and mostly injected (75%), followed by cannabis (50%), buprenorphine (47%), alcohol (23%) and benzodiazepines (22%). In Bratislava, drug use was mainly centered around pervitin (95%) and heroin (95%), and to a small extent cannabis (15%). Use of other drugs was quite low (0 to 8%). Drug use characteristics are displayed in Table 3 and Figure 2.

Table 2 - **Socio-demographic variables (n, % in brackets) per partner city and for all four cities in Imp.Ac.T. project**

	Rome			Turin	Prague	Bratislava			TOTAL		
	PDU (n=571)	*Non-PDU (n=57)*	*Both (n=628)*	(n=570)	(n=869)	PDU (n=181)	*Non-PDU (n=100)*	*Both (n=281)*	PDU (n=2191)	*Non-PDU (n=157)*	*Both (N=2352)*
Gender											
Female	99 (17.3)	*6 (10.5)*	*105 (16.7)*	113 (20.0)	282 (33.1)	79 (43.6)	*25 (25.5)*	*79 (37.3)*	574 (26.5)	*31 (20)*	*605 (26)*
Transgender	2 (0.4)	*1 (1.8)*	*3 (0.5)*	3 (0.5)	2 (0.2)	0	*0*	*0*	7 (0.3)	*1 (0.6)*	*8 (0.3)*
Male	470 (82.3)	*50 (87.7)*	*520 (82.8)*	448 (79.4)	567 (66.6)	102 (56.4)	*73 (74.5)*	*175 (62.7)*	1589 (73.2)	*123 (79.4)*	*1712 (73.6)*
Age category*											
18-24	79 (13.9)	*6 (10.5)*	*85 (13.6)*	35 (6.3)	181 (21.0)	21 (11.7)	*15 (15.2)*	*36 (13)*	317 (14.6)	*21 (13.5)*	*338 (14.5)*
25-34	175 (30.8)	*17 (29.8)*	*192 (30.7)*	127 (22.9)	486 (56.3)	95 (53.1)	*27 (27.3)*	*122 (43.9)*	884 (40.8)	*44 (28.2)*	*928 (39.9)*
35-44	206 (36.3)	*20 (35.1)*	*226 (36.2)*	233 (42)	147 (17.0)	52 (29.1)	*20 (20.2)*	*72 (25.9)*	639 (29.5)	*40 (25.6)*	*679 (29.2)*
45-54	95 (16.7)	*11 (19.3)*	*106 (17)*	139 (25)	41 (4.8)	8 (4.5)	*20 (20.2)*	*28 (10.1)*	283 (13.1)	*31 (19.9)*	*314 (13.5)*
55+	13 (2.3)	*3 (5.3)*	*16 (2.6)*	21 (3.8)	8 (0.9)	3 (1.7)	*17 (17.2)*	*20 (7.2)*	45 (2.1)	*20 (12.8)*	*65 (2.8)*
Living situation											
Homeless**	108 (18.9)	*8 (14.0)*	*116 (18.5)*	305 (54.4)	450 (51.8)	85 (47.0)	*75 (75.0)*	*160 (56.9)*	949 (43.4)	*83 (52.9)*	*1032 (44.1)*
Migrants											
Born in other country	90 (15.9)	*13 (23.2)*	*103 (16.5)*	141 (25.3)	51 (5.9)	5 (2.8)	*3 (3.0)*	*8 (2.9)*	288 (13.2)	*16 (10.3)*	*304 (13.0)*
undocumented	37	*6*	*43*	79	14	n.a.	*n.a.*	*n.a.*	n.a.	*n.a.*	*n.a.*
Education level											
no school	9 (1.6)	*0*	*9 (1.4)*	17 (3)	1 (0.1)	3 (1.7)	*0*	*3 (1.1)*	30 (1.4)	*0*	*30 (1.3)*
primary	46 (8.1)	*8 (14)*	*54 (8.6)*	125 (22.2)	391 (51.2)	102 (56.7)	*31 (32.3)*	*133 (48.2)*	665 (32.0)	*39 (25.5)*	*704 (31.5)*
secondary	282 (49.6)	*25 (43.9)*	*307 (49)*	325 (57.6)	354 (46.4)	74 (41.1)	*59 (61.5)*	*133 (48.2)*	1036 (49.9)	*84 (54.9)*	*1120 (50.2)*
higher	201 (35.3)	*20 (35.1)*	*221 (35.3)*	68 (12.1)	15 (2.0)	1 (0.6)	*6 (6.3)*	*7 (2.5)*	285 (13.7)	*26 (17.0)*	*311 (13.9)*
other	31 (5.4)	*4 (7.0)*	*35 (5.6)*	29 (5.1)	0	0	*0*	*0*	60 (2.9)	*4 (2.6)*	*64 (2.9)*
Work situation											
employed	163 (28.6)	*14 (24.6)*	*177 (28.2)*	39 (6.9)	124 (14.7)	14 (7.8)	*17 (17.0)*	*31 (11.1)*	340 (15.7)	*31 (19.7)*	*371 (16.0)*
unemployed***	321 (56.3)	*34 (59.6)*	*355 (56.6)*	392 (69.1)	634 (74.9)	103 (57.2)	*52 (52.0)*	*155 (55.4)*	1450 (67.0)	*86 (54.8)*	*1536 (66.2)*
other****	85 (14.9)	*9 (15.8)*	*94 (15.0)*	135 (23.8)	85 (10.0)	63 (35.0)	*31 (31.0)*	*94 (33.6)*	368 (17.0)	*40 (25.5)*	*408 (17.6)*

Note that subcategories do not always add up to total number of respondents in the category, this is due to missing values.

* Mean age (SD) per city: Rome 36.1 (9.5); Turin 39.5 (9.0); Prague 30.4 (7.4); Bratislava 34.7 (10.4).

** Staying on the streets or in a hostel without a steady address for one week or longer

*** This includes small groups of students and economically inactive (pensioners)

**** Category includes undeclared work and sex work (large percentage of sex workers in Bratislava).

HIV and TB related risk behaviours

Through sharing of needles or other items (cotton, wool, filter, spoon, flushing water etc) the HIV virus can be transmitted. Needle sharing behaviour was very different in the four implementing cities, as can be seen in Table 3. Active needle sharing was relatively high in Bratislava, 28% (compared to 7 to 13% in the other cities). The main reasons for sharing needles were "withdrawal symptoms", "sharing with partner", and "needle exchange not open".

More than half of the participants had ever been in prison, of which 25% had injected drugs in prison (see Table 4). The percentage IDU in prison was highest in Prague and lowest in Bratislava. As far as number of people in the cell (risk factor for TB transmission), Prague had the highest average number of people in prison cells (9.8) and Turin the lowest (2.6). However, it should be noted that these averages are estimates reported by the participants who had been to prison.

As far as sexual behaviour (see Table 5), most participants had had sex with stable partners in the last year (73%), but only 10% always used condoms with their stable partner and 74% never did this. Almost half of the participants had had sex with casual partners; 28% always used a condom with their casual partners. Sex workers used condoms more often (43% always, 20% never), and clients of sex workers also (56% always, 18% never). In Bratislava, 39% had been doing sex work, as opposed to 6% in all other three cities.

HIV Test results

In total, 2,292 rapid HIV tests were done successfully, resulting in 20 reactive results and 2272 negative results (see Table 6). Of these 20 reactive results, 5 were confirmed positive, 1 turned out to be negative (false positive), and 14 were up until October 2012 unconfirmed (participants have not yet been to the clinic).

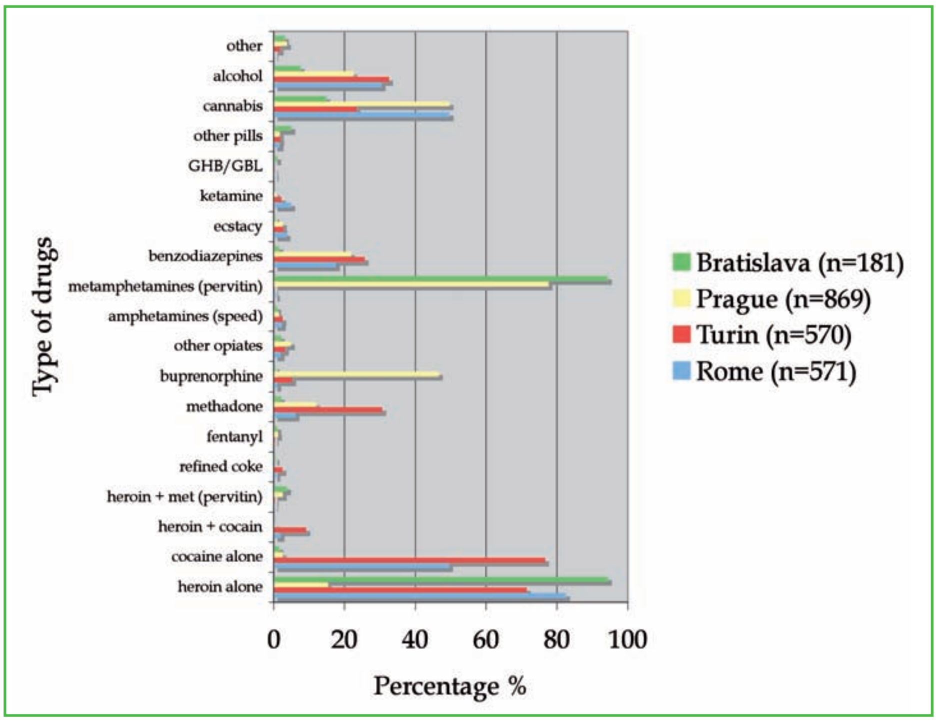


Figure 2 - *Drug use last 4 weeks*

Table 3 - **Drug use risk factors (n, % in brackets) per partner city and for all four cities in Imp.Ac.T. project**

	Rome (n=571)	Turin (n=570)	Prague (n=869)	Bratislava (n=181)	TOTAL (n=2191)
Injecting drug use					
never injected	103 (18.1)	84 (15.4)	20 (2.3)	4 (2.3)	**211 (9.8)**
ever injected	466 (81.9)	460 (84.6)	844 (97.6)	173 (97.7)	**1943 (90.2)**
last 12 months	422 (74.2)	417 (76.7)	801 (92.7)	169 (95.5)	**1809 (84.0)**
active IDU: last 4 weeks	393 (68.9)	325 (59.7)	713 (82.5)	159 (89.8)	**1590 (73.1)**
Drug use last 4 weeks					
heroin alone	472 (82.7)	408 (71.6)	134 (15.4)	171 (94.5)	**1185 (54.1)**
cocaine alone	283 (49.6)	437 (76.7)	23 (2.6)	3 (1.7)	**746 (34.0)**
heroin + cocaine	12 (2.1)	53 (9.3)	3 (0.3)	0 (0)	**68 (3.1)**
heroin + met (pervitin)	1 (0.2)	2 (0.4)	23 (2.6)	7 (3.9)	**33 (1.5)**
refined coke	5 (0.9)	14 (2.5)	0 (0)	1 (0.6)	**20 (0.9)**
fentanyl	0 (0)	2 (0.4)	11 (1.3)	2 (1.1)	**15 (0.7)**
methadone	36 (6.3)	175 (30.7)	104 (12.0)	4 (2.2)	**319 (14.6)**
buprenorphine	6 (1.1)	30 (5.3)	406 (46.7)	1 (0.6)	**443 (20.2)**
other opiates	12 (2.1)	18 (3.2)	43 (4.9)	4 (2.2)	**77 (3.5)**
amphetamines (speed)	14 (2.4)	14 (2.5)	14 (1.6)	2 (1.1)	**44 (2.0)**
metamphetamines (pervitin)	4 (0.7)	1 (0.2)	658 (77.7)	171 (94.5)	**834 (38.1)**
benzodiazepines	101 (17.7)	147 (25.8)	190 (21.9)	3 (1.7)	**441 (20.1)**
ecstacy	21 (3.7)	16 (2.8)	23 (2.6)	1 (0.6)	**61 (2.8)**
ketamine	29 (5.1)	13 (2.3)	6 (0.7)	0 (0)	**48 (2.2)**
GHB/GBL	2 (0.4)	1 (0.2)	0 (0)	2 (1.1)	**5 (0.2)**
other pills	10 (1.8)	11 (1.9)	16 (1.8)	9 (5.0)	**46 (2.1)**
cannabis	284 (49.7)	134 (23.5)	432 (49.7)	27 (14.9)	**877 (40.0)**
alcohol	175 (30.6)	186 (32.6)	196 (22.6)	14 (7.7)	**571 (26.1)**
other	1 (0.2)	10 (1.8)	33 (3.8)	6 (3.3)	**50 (2.3)**
Injecting drug use last 4 weeks					
heroin alone	363 (92.4)	344*	116 (16.3)	99 (62.3)	**922 (58.0)**
cocaine alone	163 (41.5)	305	4 (0.6)	0 (0)	**472 (29.7)**
heroin + cocaine	7 (1.8)	43	2 (0.3)	0 (0)	**52 (3.3)**
heroin + met (pervitin)	0 (0)	2	17 (2.4)	7 (4.4)	**26 (1.6)**
refined coke	0 (0)	1	0 (0)	0 (0)	**1 (0.1)**
fentanyl	0 (0)	0	10 (1.4)	2 (1.3)	**12 (0.8)**
methadone	4 (1.0)	3	23 (3.2)	0 (0)	**30 (1.9)**
buprenorphine	1 (0.3)	7	356 (49.9)	0 (0)	**364 (22.9)**
other opiates	3 (0.8)	2	28 (3.9)	3 (1.9)	**36 (2.3)**
amphetamines (speed)	0 (0)	2	6 (0.8)	0 (0)	**8 (0.5)**
metamphetamines (pervitin)	0 (0)	0	577 (80.9)	145 (91.2)	**722 (45.4)**
benzodiazepines	6 (1.5)	4	6 (0.8)	0 (0)	**16 (1.0)**
ecstacy	3 (0.8)	0	5 (0.7)	0 (0)	**8 (0.5)**

segue

segue: **Table 3 - Drug use risk factors (n, % in brackets) per partner city and for all four cities in Imp.Ac.T. project**

ketamine	6 (1.5)	1	4 (0.6)	0 (0)	**11 (0.7)**
GHB/GBL	0 (0)	0	0 (0)	1 (0.6)	**1 (0.1)**
other pills	0 (0)	1	0 (0)	5 (3.1)	**6 (0.4)**
cannabis	3 (0.8)	7	4 (0.6)	3 (1.9)	**17 (1.1)**
alcohol	3 (0.8)	9	2 (0.3)	0 (0)	**14 (0.9)**
other	0 (0)	5	11 (1.5)	0 (0)	**16 (1.0)**
IDU Needle sharing					
ever	150 (38.2)	162 (49.8)	518 (72.7)	123 (77.4)	**953 (60.0)**
Last 4 weeks	43 (10.9)	22 (6.8)	90 (12.6)	44 (27.7)	**199 (12.5)**
At follow up: last 4 weeks	3 (12.0)	2 (6.3)	18 (14.4)	10 (25.0)	**33 (14.9)**
Nr 1 reason for needle sharing	Needle Exchange not open	Withdrawal symptoms	Sharing with partner	Withdrawal symptoms	**Withdrawal symptoms**

Note that the number of answers do not always add up to the total number of interviews. Missing values ('don't know' and "refusal') have not been included in the table.

* Since this number is higher than the number of active IDU's in top of table (due to missing values?), no percentages for IDU substances could be calculated for Turin.

We managed to reach 413 people who had never been tested for HIV before (19%). Especially in Bratislava, a large percentage of never-tested persons (35%) were reached. 25 Persons had been included in the project, even though they had been found HIV positive before. These persons were included in the project because they were eligible for TB screening.

An important finding is that most of the reactive cases were found in Italy (18 out of 19, 9 in Rome and 9 in Turin). In Bratislava, one case was found and in Prague one false-positive case (confirmatory diagnosis negative). Of the 14 unconfirmed cases we do not know if there were any false positives, but we consider this unlikely based on the high sensitivity and specificity of the Determine rapid test method.

Of the 19 HIV positive cases, 12 were male, 5 female and 2 transgender. The mean age was 37 years. There were 9 homeless HIV positive cases, 4 migrant and 17 unemployed or "undeclared worker" HIV positive cases. Only 3 of the HIV positive cases had never been tested before.

Of the 19 HIV positive cases, 18 had ever injected drugs, 16 in the last 12 months and 15 in the last 4 weeks (active IDU). Drugs used in the last 4 weeks by these HIV positive cases were heroin (12) and cocaine (11) as well as cannabis (7). Only 1 out of 19 had shared needles in the last 4 weeks (5 ever). As far as sexual risk factors, 8 out of 11 cases never used a condom with their stable partner, and 2 out of 8 never used a condom with casual partners. Among the 19 infected participants, there were 3 sex workers.

We were not able to analyze differences between the HIV reactive group and the rest of the group, the number of HIV reactive cases was too small. However, at first sight, the HIV reactive group does not seem to differ substantially from the general target group population.

Follow up of patients with HIV reactive results

Five HIV reactive cases in Rome were accompanied to the clinic for confirmatory testing. Avidity testing was done for four cases, one is still awaiting results. Three infections appeared to be early infections (infection less than six months ago), and one infection was an late infection (infection longer than 6 months ago).

Table 4 - Prison (n, % in brackets) per partner city and for all four cities in Imp.Ac.T. project

	Rome (n=571)	Turin (n=570)	Prague (n=869)	Bratislava (n=181)	TOTAL (n=2191)
Prison					
ever been in prison	300 (52.7)	352 (62.0)	360 (41.5)	121 (67.2)	**1133 (51.9)**
IDU in prison	33 (11.0)	108 (30.4)	139 (38.6)	9 (7.4)	**289 (25.4)**
Average number of people in cell (SD)	4.7 (4.0)	2.6 (5.5)	9.8 (10.0)	8.4 (8.1)	**6.1 (7.0)**

Table 5 - Sexual contact risk factors (n, % in brackets) per partner city and for all four cities in Imp.Ac.T. project

	Rome (n=571)	Turin (n=570)	Prague (n=869)	Bratislava (n=181)	TOTAL (n=2191)
Sexual contact					
last 12 months	503 (88.4)	380 (67.0)	734 (84.6)	154 (85.1)	**1771 (81.1)**
stable partner	384 (76.3)	240 (62.8)	545 (74.1)	120 (78.4)	**1289 (72.7)**
casual partner	242 (48.3)	166 (43.9)	390 (53.1)	57 (37.5)	**855 (48.4)**
as sex worker	32 (6.3)	24 (6.3)	44 (6.0)	59 (39.1)	**159 (9.0)**
as client of sex worker	41 (8.2)	33 (9.1)	32 (4.4)	19 (12.7)	**125 (7.2)**
Condom use					
stable partner: always	35 (8.4)	37 (15.0)	39 (7.2)	20 (12.4)	**131 (9.6)**
stable partner: never	329 (78.7)	172 (69.6)	404 (74.1)	111 (68.9)	**1016 (74.1)**
casual partner: always	91 (34.1)	50 (29.8)	88 (22.7)	22 (24.7)	**251 (27.5)**
casual partner: never	42 (15.7)	48 (28.6)	58 (14.9)	15 (16.9)	**163 (17.9)**
as sex worker: always	10 (33.3)	5 (15.6)	25 (56.8)	36 (49.3)	**76 (42.5)**
as sex worker: never	13 (43.3)	7 (21.9)	8 (11.0)	8 (11.0)	**36 (20.1)**
as client of sex worker: always	33 (73.3)	15 (44.1)	20 (64.5)	8 (30.8)	**76 (55.9)**
as client of sex worker: never	7 (15.6)	2 (5.9)	8 (25.8)	7 (26.9)	**24 (17.6)**
Diagnosed with STD within last 12 months	22 (4.4)	41 (11.0)	28 (3.8)	10 (6.5)	**101 (5.7)**

As far as treatment, three out of five cases in Rome have started follow up testing or treatment. One person has started HAART medication. For one other person who had an acute HIV infection, HAART was not required, but this person has starter regular visits and examinations.

Another person is still awaiting confirmatory and avidity testing results, but showing up at visits. As far as the other two infected persons (a couple), one of them has been arrested, and the other did not show up at the clinical centre for follow up appointment. Up until now, contact with these two persons has been lost.

The data of the follow up of HIV reactive cases in Turin were not available at the moment of writing. In Bratislava, contact with the one HIV reactive case was unfortunately lost up until now (his mobile phone was not working anymore).

Unfortunately we were not able to analyze behavioural or demographic differences or main determinants regarding late or early presentation for testing, and regarding late/ early access to treatment, due to the small number of cases.

TB Test results

All participants in the project were screened for TB symptoms and risk-factors. For 106 participants, the result of the screening was positive, which meant that these participants should be tested for TB. In Prague, the 46 participants that qualified for TB testing, were referred to the clinic for x-ray. Of 9 people the result of this clinical testing was negative, of the other 37 participants the results are still unknown, see Table 6. In the other cities, sputum was collected of 55 participants. We succeeded to collect a second sputum sample with 6 participants. All sputum samples were sent to the lab. Results were negative in all cases.

However, one case of latent TB was found among the HIV reactive cases that were referred to the clinic for follow up. In our project TB screening, this person had not been deemed eligible for sputum testing, since he was taking antibiotics for bronchitis. When he was examined at the clinic, three sputum samples were collected, all were negative. However, quantiferon blood test revealed that prophylactic TB medication was required.

Attitudes and behaviours regarding HIV and TB testing

Attitudes and behaviours regarding HIV and TB testing were measured both qualitatively (in the focus groups) and quantitatively (in the questionnaires). In the questionnaires, questions regarding testing history were asked first. For HIV, 79% had been tested before. For TB, quite a large percentage was vaccinated (49%) or possibly vaccinated (not sure, 26%); furthermore 53% had ever been tested before. Again, quite large differences between the four cities were observed. The main reasons for participants not to get tested before, was “I don’t think I’m infected”, and in the Italian cities, “other priorities (e.g., need to take drugs)” was a good second reason. Participants indicated that the main reason to get tested now, was “The test was offered to me, I did not have to go after it myself”; in Bratislava and Turin a good second reason was “the test is free of charge”.

The participants that were re-interviewed and re-tested, indicated that their main reason for doing so was “I was reminded by social workers/nurses” (Turin and Rome) or “I calculated that 3 months had

Table 6 - Test results per partner city and for all four cities in Imp.Ac.T. project

	Rome (n=571)	Turin (n=570)	Prague (n=869)	Bratislava (n=181)	TOTAL (n=2191)
HIV					
Rapidtest successful	563	545	849	179	**2292**
HIV rapid test reactive	9	9	1	1	**20**
Not tested because already HIV positive*	2	21	1	1	**25**
Confirmatory HIV diagnosis					
Positive	4	1	0	0	**5**
Negative	0	0	1	0	**1**
Started treatment	*3*	Not yet	-	Not yet	
Newly diagnosed HIV infections **					
among Active IDU (in last 4 wks)	5/393	9/325	0/713	1/159	**15/1590**
among Recent IDU's (12 months)	6/422	9/417	0/801	1/169	**16/1809**
Among PDU's (target group)	9/571	9/570	0/869	1/181	**19/2191**
TB					
TB screening positive	30	8	46	22	**106**
TB screening negative	536	543	809	157	**2045**
Sputum 1 collected	23	10	0***	22	**55**
Sputum 2 collected	1	0		5	**6**
Result sputum 1 pos	0	0		0	**0**
Result sputum 2 pos	0			0	**0**
Result sputum 1 neg	23	8		22	**53**
Result sputum 2 neg	1	0		5	**6**
Confirmatory TB diagnosis					
Positive	0	0	0	0	**0**
Negative	0	2	9	0	**11**
Not reached/ don't know	0	3	34****	0	**37**

* Not every participant in project was tested for HIV. Some participants were HIV positive but were eligible for TB-testing, and were included in the project for that reason.
** Based on rapid test results and confirmatory results, if available; no reactive/positive HIV test result before.
*** No sputum testing in Prague (legal constraints).
**** In Prague TB suspect cases were referred to the clinic for thorax; follow up was difficult.

passed since the last test" (Bratislava and Prague). Participants preferred being retested within Imp.Ac.T. over getting a test at the regular facilities, because it was easier for them in terms of access. Relatively small groups indicated that they were not comfortable to go to the regular facilities for follow up HIV testing (13%) or TB testing (10%) because of their drug use (13 persons) or because they did not think they would become infected (9 persons). The latter reason was also the main reason for people not to go to the clinic for follow up TB testing (81 persons). Nevertheless, 72% indicated that they would go to the regular facilities for follow up HIV testing. Not surprisingly, the intention to continue TB testing was much lower (22%).

Regarding behaviour change, 23% indicated that their behaviour regarding HIV risks (condom use, needle sharing) had changed "a lot" or "completely" since the first interview (in which they also had received counselling and education on risk prevention). Another 14% indicated their HIV risk behaviour had changed "a little". The other 60% felt their HIV risk behaviour had not changed at all. This could be due to the fact that a lot of participants had already been tested for HIV before and a lot of drug users that are clients of the low threshold centres are familiar with HIV through other health programmes. For TB, 78% indicated their knowledge of TB infection had not changed at all since the first interview. This is surprising, because in the focus groups it became apparent that knowledge on TB was not rich among the target group, and that the education session was most welcomed (see next paragraph).

At follow up, not only attitudes regarding testing were measured, but also actual risk behaviour (only for HIV). At first follow up, needle sharing had slightly decreased in Turin and Bratislava, but slightly increased in Rome and Prague. Since the number of participants answering this question was low (33 persons), and follow up time was relatively short (a couple of months after the first interview), this finding is not reliable and cannot be interpreted. As far as sexual behaviour and condom use, no significant differences between first and follow up measurement have been found.

Qualitative results from the focus groups

In total, 16 focus groups were held (4 in each city) with a sum total of 115 participants (see Table 7). It was sometimes quite hard to find participants and circumstances were not always ideal. For example, some focus group sessions were held in the open air or in a car. Despite strict instructions (and after consultation with the researcher), 4 focus groups were held with less than 6 participants. In those instances, it had been impossible to find more participants - let alone try to get a representative balance in the sample - even after trying to reschedule another focus group session. In three cases, the number of participants was more than 10. Findings from all focus groups were considered valuable and therefore taken into the analysis. Participants were mostly male (76%) and on average 35.7 years old. In total 24 migrants (21%) took part in the focus groups.

TB knowledge

Most participants considered TB to be "a disease from the past" which has been eradicated. Knowledge on symptoms, transmission and protection was in general low to moderate, usually only one or two participants of the focus groups had some knowledge through second-hand experience. Participants mostly did know that it's an infection of the lungs and that it involves coughing.

Table 7 - Focus group characteristics

	Rome	Turin	Prague	Bratislava	**TOTAL**
Focus group 1: TB knowledge and access to TB testing and treatment					
Number of FG participants	11	6	8	4	**29**
Number of males	10	6	4	3	**23 (79%)**
Number of migrants	3	4	0	0	**7 (24%)**
Mean age	38.0	29.5	28.8	43.0	**34.4**
Focus group 2: HIV knowledge and access to TB testing and treatment					
Number of FG participants	12	11	7	4	**34**
Number of males	9	9	4	3	**25 (74%)**
Number of migrants	3	6	1	0	**10 (29%)**
Mean age	38.7	36.6	25.1	43.0	**35.7**
Focus group 3: HIV and TB - non Imp.Ac.T. participants					
Number of FG participants	5	8	4	6	**23**
Number of males	5	7	2	5	**19 (83%)**
Number of migrants	0	0	1 (Slovak)	0	**1 (4%)**
Mean age	35.4	41.1	33.5	23.8	**34.0**
Focus group 4: HIV and TB - Imp.Ac.T. participants					
Number of FG participants	8	7	6	8	**29**
Number of males	8	5	5	2	**20 (69%)**
Number of migrants	3	1	2 (Slovak)	0	**6 (21%)**
Mean age	37.3	44.0	38.7	33.5	**38.2**
Total of all focus groups					
Number of FG participants	**36**	**32**	**25**	**22**	**115**
Number of males	**32 (89%)**	**27 (84%)**	**15 (60%)**	**13 (59%)**	**87 (76%)**
Number of migrants	**9 (25%)**	**11 (34%)**	**4 (16%)**	**0**	**24 (21%)**
Mean age	**37.7**	**38.0**	**30.9**	**34.3**	**35.7**

> *"What do you know about TB? – Nothing. […] It is pulmonary disease, no?" (BR)*
>
> *" Something is expectorated. Blood is expectorated." "The person is breathing hardly." (BR)*

In Prague, knowledge seemed slightly more advanced, the conversation progressed to a deeper level of trying to understand how the virus works:

> *"If I am right, there are more kinds of TB. One of them is open, […] one is worse and one is moderate, if I remember it well… the open one is incurable maybe." (PR)*
>
> *" It comes up to break-up of pulmonary alveoli, during the rapid stage of coughing it also comes up to coughing up blood." (PR)*

Some people confused transmission routes with those of TB (sexual transmission is often mentioned), and some people thought TB is a symptom of HIV. A few individuals showed richer knowledge because they knew people who were treated for TB, but most participants had incorrect or incomplete information about TB transmission and how to protect themselves against the virus.

> *"I remember one case when I was in jail, but I wasn't concerned about it. If you don't have sex or exchange needles you are also safe from TB, isn't it?" (TU)*
>
> *"I don't know how to protect [myself from TB], maybe with the tuberculin skin test…" (RO)*
>
> *"I think, person can catch from someone else, but it can also be induced by the environment." (BR)*
>
> *"Avoid people with dirty hands."(PR)*
>
> *"This vaccination has some limited time when it works. Then you need to get a new one."(PR)*
>
> *"I've heard it can be cured, by eating more fat food, milk, and the dogs fat is healthy for it, it is on sale in pharmacies."(BR)*

In all TB focus groups, questions were asked by participants about TB. Moderators were instructed not to answer any questions during the focus group and refer to an education session at the end of the focus group. Reasons for lack of knowledge on TB were attributed to lack of education or interest:

> *"Yes, I also think that information is very low, it's not considered a serious problem, there is no risk perception."- "It's not only a question of being drug users or not, the point is having a general medical education or not…" (RO)*
>
> *" You have no reason to be interested. Why? Until I'm not affected, I don't care." (BR)*

Furthermore, in several focus groups questions were asked regarding other infectious diseases, such as hepatitis (Rome, Prague, Turin) or syphilis (in Prague). Participants expressed more interest in talking about these other infectious diseases.

Access to TB testing and treatment

Access to TB testing is most often not considered a problem, people know where to go (general practitioner, hospital). Barriers to healthcare are sometimes attributed internally:

> *"If you have a strong motivation there are no problems. – Yes, I think there are no problems both for Italians and foreigners." (RO)*
> *"Illegal migrants are at risk because they don't like to go to hospitals."(TU)*
> *"…little bit of aloofness, phlegmatic.." – "Man want to be tested, but he postpones, still delays and then he realizes that he put it off for three months." [What's the reason for this?] "Nature of the guy, who had to arrange his business, he doesn't arrange anything, I will do it tomorrow type, just postpones."(PR)*

However, also some more general institutional obstacles in getting healthcare are mentioned, like bureaucracy and the long procedure for testing, but also feelings of being discriminated against are expressed:

> *"The doctor tells you to make the test and then you need to make a long bureaucratic procedure to get it. When I did the test and went for the result, the doctor that was there did not want to read me the result because he was not specialised in TB, so I needed to wait some other days in order to get it…If I was infected I would have infected other people."(RO)*
> *"If you will not pay, you do not get [treatment], you can even die."- "It is about the approach. There are doctors and doctors."(BR)*
> *"When a doctor finds out I am a drug user, he tries to postpone the examination. It happens in […] hospital. I was lying with 40 degrees fever for 5 hours in the corridor." (PR)*
> *"During the communist era we [drug users] were treated like non-human beings. Things are different now, but some people are still the same." (PR)*

Quite a few participants have been tested, either with TST (mantoux) or x-ray; it sometimes was a condition to enter a night shelter or a rehabilitation centre, or they were tested in prison, or they took part in a contact screening around a TB positive case. However, even people who were tested did not know a lot about TB or the test:

> *"When I did the TST, they used a syringe and then a bubble came out on my arm. Is it possible that it happened because I had occasional sex with a girl?" (RO)*

As far as access to treatment, the fear of treatment in isolation (for those that know about quarantine) is mentioned sporadically; some participants are afraid of withdrawal symptoms. No other new barriers are mentioned for access to treatment.

HIV knowledge

For HIV, knowledge on symptoms, transmission and protection was on average relatively rich, certainly in comparison to knowledge on TB.

Some participants showed low levels of knowledge, but they were almost always corrected by other participants. Participants commented that drug users are often more aware of risks than the general population.

> *"You can get it through infected syringe and unprotected sex."(RO)*
>
> *"New generations medicines are enough strong to eliminate infection… Not really to eliminate, but allowing infected person to live quite normally, without taking too many risks. Of course you have to follow therapy strictly." (TU)*
>
> *"The ones who have it, should be isolated, when they find it out. So they wouldn't walk out."- "It is not like that, that you can catch it by holding hands." (BR)*
>
> *"You have to take precautions. That means… transmission is through blood, seminal fluids, so sperm, but not trough spit or sweat, while many people who don't know maybe they are also afraid of that."(TU)*
>
> *"You feel safe just because you take pills and you don't shoot up? But don't you have sex? Are there no risks in your life?"(TU)*

In Prague, the discussion became more technical, about the virus attacking white blood cells. However, the level of knowledge seemed lower with some participants in Prague than in the other cities (for example, transmission through saliva was mentioned), but this might also be due to the fact that three participants were mental health patients and three participants were obviously intoxicated during the focus group on HIV.

Access to HIV testing and treatment

Barriers to HIV testing were mostly attributed to themselves: they felt that members of the target group who do not get tested for HIV might be scared; the fear of being infected was the main reason according to most participant, or the opposite: the underestimation of risk. Also shame and indifference were mentioned in each focus group, as well as other priorities (getting drugs).

> ***"What could be the reasons why people don't want to get tested?"***
>
> *"Because they are afraid! Or they don't care."(RO)*
>
> *"[…]but I am not coming [to get tested] at present, because I am afraid that something will be diagnosed." (PR)*
>
> *"You feel ashamed to go to test and you are afraid to be positive." (TU)*
>
> *"If you care about yourself, you can wait [15 days to get the test result]. The point is that drug users don't love themselves, don't respect themselves."(RO)*
>
> *"I was afraid of what people can think…"(TU)*
>
> *"lack of time."(BR)*
>
> *"If you are an active drug user and must choose between going to the hospital for taking the results [of the HIV test] and going to buy drug and use it, you choose drug!"(RO)*

Most people agree that the barriers are mainly in the people, while institutional barriers are less important. In Bratislava (but not in the other cities) institutional barriers were mentioned in the form of (perceived) stigmatisation of drug users as far as HIV testing and treatment.

> *"They are afraid, how they will be accepted by doctors, if they accept them or not."(BR)*
>
> *"Drug users do not have place to stay. ID cards, health care insurance cards[…], the approach to drug users should be totally different. They start to scream on them and the person run away." (BR)*
>
> *"[…]if there would be such an organisation, which would help him to take over his stuff […], to go to doctor with him and can speak in the name of that person. Some people don't know how to formulate it. "(BR)*

Change in knowledge, behaviour and attitudes

After implementation, focus groups were held with (1) people who were tested within Imp.AcT. and (2) people who were not tested in Imp.Ac.T., in order to identify possible changes in behaviour, attitudes and knowledge. Obviously, the Imp.Ac.T. participants would have had education about HIV, TB, testing and treatment as part of the counselling. The focus group with participants who had not been tested within Imp.Ac.T. could show if attitudes, knowledge and behaviours had been changed in the year of implementation, irrespective of taking part in the project or not.

The knowledge, attitudes and behaviours of non-Imp.Ac.T. participants seemed more or less the same before and after implementation, in all cities, and this was similar for HIV and TB. Participants that took part in Imp.Ac.T., also agree that the level of information has not changed so much from last year, but some think there should be more education and/or talking about HIV and/or TB.

> *"What I know today is the same I have known a year ago"(TU)*
>
> *"I've had the possibility to talk more deeply with the doctor, I'm less concerned about HIV because I know a little bit more about it now."(TU)*
>
> *"Only from such institutions [low threshold centres] or from leaflets [I have gotten information]." (PR)*

Evaluation of Imp.Ac.T. project by participants

The testing was evaluated as very positive in Bratislava, Rome and Turin. In Turin and Prague the incentives were mentioned specifically as a positive thing (phonecard or meal ticket).

"It was good, at least for me, if I have not find it maybe I would have delayed the HIV test more, and now I know more about TB." (TU)

"It's very good. Considering the life we do, if I know that I'm not ill I try to be more careful."(RO)

"And it's also good that it's a rapid test, so you don't spend 10-15 days with fear and anxiety."(RO)

The most prevailing criticism on Imp.Ac.T. was that HCV was not tested, this was mentioned in all cities (in Prague and Bratislava they did offer HCV testing, but not as part of Imp.Ac.T.). Other comments were the following:

> *"It is bad to start [a project like this] and then stop [again]". (TU)*
> *"Only the questions of that form were boring, you asked always the same things… But I think they are useful for statistical data." (RO)*
> *"Still [you should] draw their attention to it [HIV and TB testing]!"*.

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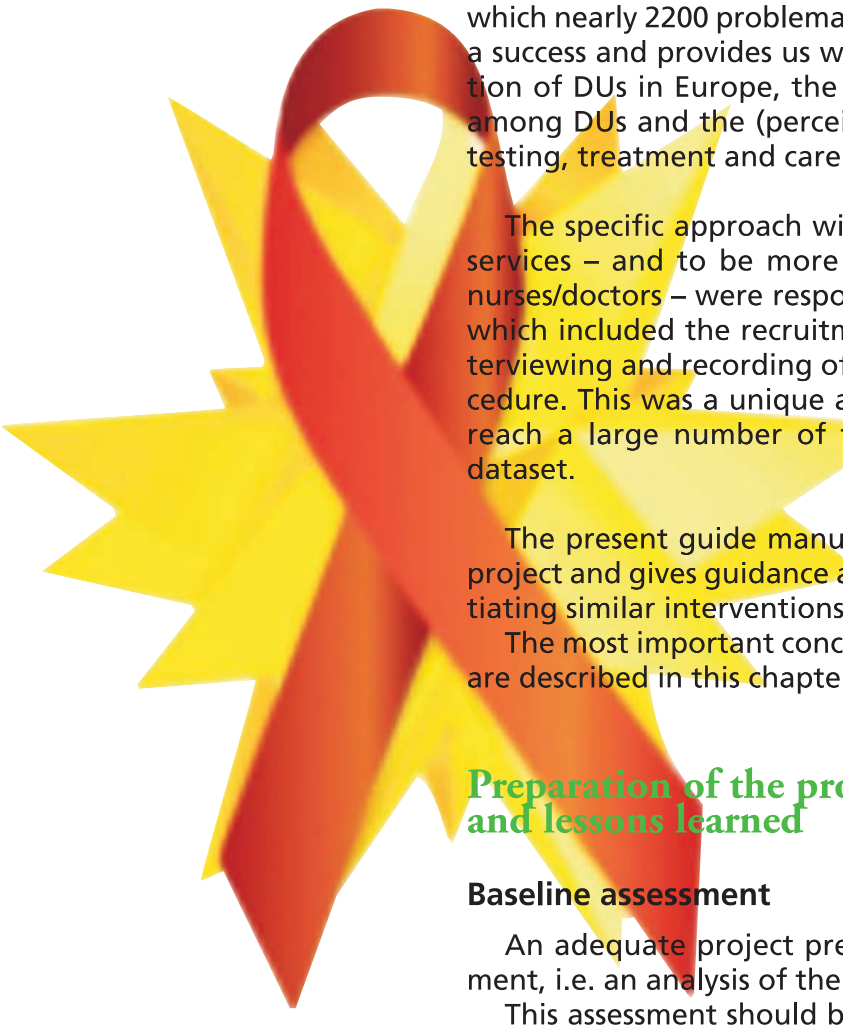
1 Test results from F,T, or Chisquare tests will not be mentioned in this chapter, but will be published elsewhere and can be delivered on request.

2 Analysis have not yet been double checked at the time of writing. Minor changes in percentages reserved to the author

Chapter 7

Conclusions



The Imp.Ac.T. Project interviewed and tested nearly 2350 people, of which nearly 2200 problematic drug users (PDUs). This on itself is already a success and provides us with new and vital information on the situation of DUs in Europe, the HIV and TB prevalence and incidence rate among DUs and the (perceived) barriers for DUs to access HIV and TB testing, treatment and care.

The specific approach within Imp.Ac.T. has been that low-threshold services – and to be more specific social workers, psychologists and nurses/doctors – were responsible for the implementation of activities, which included the recruitment, the pre- and post-counselling, the interviewing and recording of data as well as the TB and HIV testing procedure. This was a unique approach which offered the opportunity to reach a large number of target group members and collect a rich dataset.

The present guide manual describes the most relevant parts of the project and gives guidance and support to other service providers in initiating similar interventions.

The most important conclusions and lessons learned within Imp.Ac.T. are described in this chapter.

Preparation of the project: core principles and lessons learned

Baseline assessment

An adequate project preparation should include a baseline assessment, i.e. an analysis of the local situation and a needs assessment.

This assessment should be carried out before the project is initiated and before the partners are selected. A thorough baseline assessment enables the implementing organizations to develop a realistic working plan.

In Imp.Ac.T., desk research was done and needs were assessed in the preparatory stage of the proposal; a more thorough baseline assessment was done after the start of the activities. In hindsight, we believe it would have been better if the baseline assessment would have been done more thoroughly before the start of the project.

The baseline assessment should be based on international, national and local epidemiological and demographical data (e.g. prevalence and incidence of HIV and TB), as well as expert consultation (including policy makers, service providers, researchers, epidemiologists and target group representatives).

All the Imp.Ac.T. partner organizations seemed to have difficulties to collect epidemiological data and information in regard to the TB prevalence and incidence rate, both among the general population and drug users in particular. It was assumed that TB is a major problem among DUs, based on general European findings that proportions of TB-HIV co-infections range from 2 to 15% in the EU[1].

However, in the participating cities TB did not seem to be a big problem among the target group. The baseline assessment did not provide conclusive information, and a pilot project like Imp.A.c.T. could provide more insight into TB prevalence among drug users.

During the project implementation, it is resulted that hepatitis C is considered a major health problem among drug users (in particular injecting drug users). This finding should be taken into account when planning other similar interventions among this target group: besides HIV testing and counselling, also the testing for hepatitis C should be provided.

Active and early involvement of relevant local partners

The involvement of additional local partners at an early stage is essential. Additional partners can be the clinical centres, health services, laboratories and other low threshold services, which might cooperate with the implementing organizations.

Involving these additional partners at an early stage will improve the methodology of the project, the practical collaboration on the local level, as well as the commitment of these partners to reach the planned objectives and results. Furthermore, it will contribute to facilitate the access of clients to treatment and care, namely the follow-up, which proved to be problematic in most of the participating cities.

Imp.Ac.T. involved 4 implementing organizations, all of them responsible for the carrying out of activities in their city. Additional local partners were involved, such as clinical centres for HIV and TB and other low-threshold services for drug users. They provided input during the development of the testing algorithm and the study protocol, particularly regarding the definition of TB testing methodology. However, more involvement of the collaborating partners would have been beneficial to the project.

Additional expertise would have been useful, especially because there was only a small group of medical experts available during the meetings.

Involvement of additional experts

Besides the involvement of national experts and collaborating partners, who can support the implementation on the local level, it is important to involve also international experts.

Imp.Ac.T. set up an Advisory Board with various international experts, all of them with specific expertise in different areas. All partner organizations considered the input of the Advisory Board as useful, but it was also mentioned that more involvement would have been desirable.

Development of the project methodology and the study protocol

The development of a detailed and comprehensive methodology and study protocol is essential. The methodology should be based on the review of existing evidence and should take into account specific needs of the target population as well as potential limitations of the service providers, which provide the testing. In addition is important to be aware of legal boundaries and to set up a supportive local network, which is involved in the planning and implementation of the project.

Within Imp.Ac.T., it was managed to develop a methodology to which all partners could comply (except some changes in the Czech Republic, where it was not possible to do sputum tests and referral to x-ray was the proposed method for TB-testing). Although the partners were satisfied with the methodology, it did take a long time to develop it. It might have been possible to speed up this phase, if the methodology had been developed only by medical experts in cooperation with the health professionals and social workers working in low-threshold services.

Project monitoring tools

To ensure an effective and measurable intervention it is essential to develop and establish regular monitoring tools. This will enable the project coordinators to monitor the progress in the activities implementation and to evaluate them properly.

Imp.Ac.T. established a framework matrix and activity lists, which supported the evaluators and the coordinators in monitoring the project progress. In addition, output and outcome indicators were determined, to enable the researcher to develop tools for data collection (e.g., testing behaviour and attitudes toward testing and treatment of the target group), thereby assessing results of the project.

The monitoring tools were complemented by evaluation interviews, organised after 1 year and after two years This additional method provided useful information on the progress of the project and gave insight about perceived barriers and problems. We started out with three-monthly process evaluation forms, but this was too time-consuming and not informative enough. Therefore we decided to change the evaluation method from questionnaires to qualitative interviews, and this proved more useful for us. It is important that process is monitored and the coordinator is aware of the activities in all locations, however this does not need to be formalized in three-monthly forms. Regular check-ups by e-mail and skype combined with more in-depth qualitative interviews seem to be more efficient.

Training

The training of staff members was an essential part during the preparation phase of Imp.Ac.T. All partners contributed actively to the content of the training manual. Partners trained their staff in regard to the developed common methodology, the recruitment of clients for the testing, the follow-up, as well as the data collection and recording.

The training content was the same for all partners, but all partners adapted their training to the local and organisational needs (after consulting with the project coordinator).

The experience within Imp.Ac.T. has shown that it is extremely important to organise regular team meetings, to monitor the needs of the workers and to offer regular and continuous training.

Some workers experienced major problems in combining their work as social worker with the role as interviewer and data collector (see chapter 5 for a description). This particular issue has been addressed in specific training sessions, which were scheduled during the implementation phase.

Implementation of HIV/TB testing: core principles and lessons learned

The implementation started after the development of the study protocol, the establishment of data collection tools and the training of the staff members.

The implementation phase included the recruitment, the counselling and testing, the follow-up and the data collection and recording.

Recruitment

The recruitment was carried out by the outreach workers in low-threshold settings. Although it has not been investigated, it might have been useful to involve DUs as peers for the recruitment and to see if this approach would have increased the final sample size and the motivation of PDU's to enrol in the project. Existing evidence could plead for such an approach in the future[2 3].

Three partners decided to give incentives and rewards (phone cards and food tickets) to increase the motivation of DUs to enrol in the project. All of them reported an increased motivation among the participants, which leads to the assumption that incentives work well for this particular target group.

It has to be acknowledged that low-threshold settings are strongly affected by external factors, such as the weather and the presence of police on the streets. All partners reported external factors, which created additional barriers for the recruitment of participants. The Slovakian partner for example had to deal four times with the deliberate destruction of their mobile unit. It is therefore advisable to include potential barriers in the very beginning as part of the baseline assessment. In some countries it might also be useful to include the police as collaboration partner.

Counselling and testing

All Imp.Ac.T. partners stressed that it has been important to include TB in the project, because knowledge on TB was very poor among our target group. Partner organizations also admitted that they learned a lot about TB and could increase the awareness and the knowledge about the disease among their workers and the target group. However, no active TB was found (only one case of latent TB). It could be the case that TB is very low in prevalence among the target group in the participating cities, or the methodology could have been insufficient in order to detect TB. In the first case, this is good information and a positive outcome. If our testing method (screening + sputum) has not been good enough in the sense that TB positive cases were missed, this would have been a missed opportunity. Unfortunately, we cannot be 100% sure that we did not miss TB positive cases, especially not TB latent cases.

The TB testing methodology was a point of critique. None of the discussed and suggested methods seemed to be ideal, and we dedicated several meetings to discussing them with experts and with the partners. Finally, it was decided to conduct a clinical TB screening, followed by a sputum smear collection (in suspect cases). The main problem which was finally encountered with this methodology was the collection of a second sputum smear. Participants did not show up for a second test, which reduces the reliability of the final testing results. This applies as well to the adapted methodology in the Czech Republic, where suspect cases were directly referred to the hospital for an X-Ray (due to legal obligations). They mostly never showed up. Another problem was that the screening for symptoms had to be done by a medical doctor or a nurse, which sometimes meant that new people had to be hired by the partner organisations, which took some time.

Ideally, a mobile X-Ray would have been the most advisable, but taking into account the costs of such an intervention, this was not an option. The TB skin test has also been discussed, but was rejected, as many participants have been vaccinated (without knowing) and would also not return for being checked for the results. After consultation of several experts, we decided to test for active TB and not latent, and chose the method that was considered the best, least costly and most efficient. The question remains whether we made the right choices in developing TB testing methodology.

Regarding HIV testing, the use of the HIV rapid test worked well, but it is recommended to use other methods for confirmatory testing as well, such as the blood analysis on the spot or the use of a second rapid test for confirmation[4]. In this way, clients do not need to come back for follow up or be referred to other health centres, with the risk to get lost for follow up.

The multi-professional approach was beneficial for the project and the target group. Different professions could support each other and provides specific complimentary expertise.

Selecting places for testing where people never have been tested before, will increase the notion and the effectiveness of this intervention.

Follow-up

It has been one of the major problems during the project to ensure follow-up. Therefore, one of the most important recommendations should be to cooperate closely with other local partners. It is not enough to involve them during the course of the activities. They should also be part of the planning and preparation phase to become more committed to the project and the target group; this might increase their flexibility and willingness to offer tailored services to marginalized groups such as DUs.

Anyway, the project has showed that motivating drug users toward their own health status requires specific efforts and skills. It is a process that implies long time, constant assistance and support, and real commitment from the service providers.

Data Collection

The data collection within Imp.Ac.T, has been embedded in the regular services of the partner organizations. It was an important project principle, that the research activities should not intervene with the practical work too much, but rather be complementing to it – as a logical extension of the regular activities, providing research data.

This also means that the research methods had to fit to the working conditions and to the target group. All the partners were clear about it: the research element should be beneficial for the (future) work and the target group. Project partners did not want to collect data, without having practical added value.

The combination of research and practice worked well, although it is obvious that it has not always been unproblematic. Some outreach workers seemed to have problems with combining their work as social workers with the role of interviewer. This again pleads for decent training and cooperation among staff members. It is also advisable to have a researcher at the spot, who could support workers and supervise the data collection more closely.

Within Imp.Ac.T. several data collection tools were used. The data of the questionnaires were recorded in an online database, which could be accessed by all partners (only their own data could be modified). The online survey tool which has been used by the Czech Republic only, enabled the workers to fill in the data directly at the spot, without having double work and risking loss of data.

The Response Monitoring Form was considered to be very time-consuming and some workers experienced it as quite disturbing for the overall working process. It is therefore questionable, if such a tool should be used in the future, even though it has clear benefits (see also chapter 5).

Results and conclusions

It is evident that Imp.Ac.T. managed to test a large number of DUs on HIV and TB. It can also be assumed that the provision of low-threshold testing has been useful and effective for hard-to reach groups: almost 20% of the people tested in the framework of Imp.Ac.T. were never tested before for HIV.

We have found 19 HIV reactive cases, of which 15 were active IDU's.

For active IDU’s, the newly diagnosed cases within the project reached 1%. If this would reflect real incidence in terms of percentage of new infections within our target group (and there are good reasons to do so), these data are quite alarming. Only one HIV positive case was found in Bratislava, none in Prague; the largest group (18 participants) came from Italy.

Although TB might not be a problem among DUs in the four participating cities, it has been useful to collect these data. There was a lack of knowledge and information and the project created more evidence and more awareness about TB among outreach workers and the target group. Furthermore, experience has been gained in using our testing methodology, which is useful knowledge for future projects.

The target group rated the project as positive. They were satisfied and happy about the services, although many of them considered Hepatitis C as more important, which might give an idea for future actions in the field.

Those, who were not tested, reported that they had no time (mainly due to their drug addiction) or that they were afraid of the testing result. It is interesting that most of the respondents did not complain about barriers to access. If they did so, they often ascribed barriers to themselves. Some reported bad attitudes among the medical staff in the clinics, which made them feel stigmatised.

Recommendations for future actions

The most important recommendations for future projects can be summarized as followed:

- A thorough project preparation is essential. Baseline assessment and partner choice should be evidence based and/or experience based, before the outset of the project. It is advisable to involve researcher(s) and/or an advisory board at an early stage when indicators and research questions are still being developed. Also, local partners (clinics, labs) should be involved in the development of the project, since they are essential in lowering thresholds in access to follow up testing and treatment on a more structural basis. Also, they have a lot of knowledge on what is possible and what is not, in terms of testing and communication about results etc.
- The methods of testing and research should be tailored to the target group and the people performing the tests, the counselling and the data collection. Good training of workers is crucial. There should also be monitoring or supervision so that problems with data collection, role conflicts or other issues can be identified in an early stage and actions can be taken.
- Methods of testing and research should be developed with experts, that is: researchers, medical experts, social workers, and preferably also members of the target group. Input of all these experts is important. However, in order to have a more efficient development of methods, experts from the collaborating clinics could have been responsible for deciding on testing methods.

- Peer involvement in the recruitment phase could be useful. Using incentives could also be good for getting more participants for follow up testing (increasing incentives).

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1 WHO Report 2009 – Global tuberculosis control.

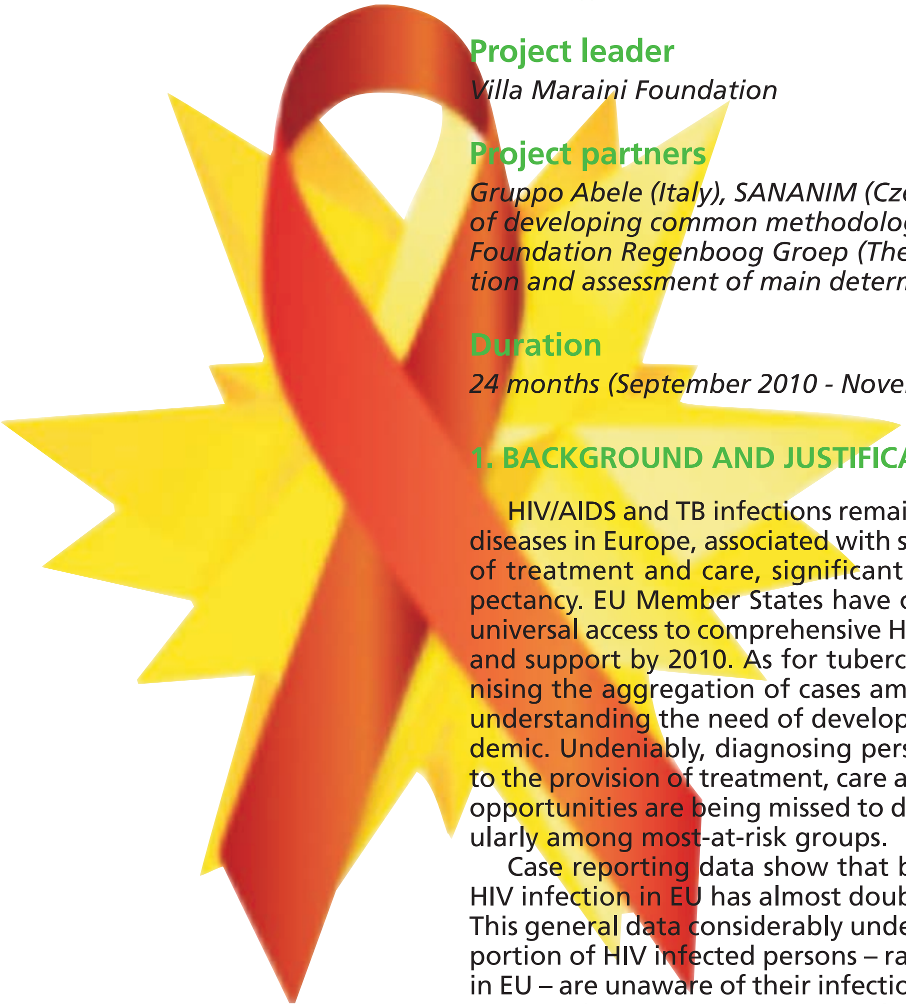
2 Broadhead, R.S., Heckathorn, D.D., Grund, J-P., Stern, L.S., et al. (1995). Drug users versus outreach workers in combating AIDS: Preliminare results of a peer-driven intervention.

3 www.peerinvolvement.eu.

4 HIV Testing Algorithms: A Status Report, Association of Public Health Laboratories and The centers for Disease control & Prevention, April 2009.

Annex I
The study protocol

Study protocol



Project leader

Villa Maraini Foundation

Project partners

Gruppo Abele (Italy), SANANIM (Czech Republic), Odyseus (Slovakia): in charge of developing common methodology and implementing HIV and TB testing. Foundation Regenboog Groep (The Netherlands): in charge of project evaluation and assessment of main determinants.

Duration

24 months (September 2010 - November 2012); testing phase: 13 months

1. BACKGROUND AND JUSTIFICATIONS

HIV/AIDS and TB infections remain one of the most important communicable diseases in Europe, associated with serious consequences, persistently high costs of treatment and care, significant number of deaths and shortened life expectancy. EU Member States have committed themselves towards the goal of universal access to comprehensive HIV prevention programmes, treatment, care and support by 2010. As for tuberculosis, EU countries are increasingly recognising the aggregation of cases among particular vulnerable populations and understanding the need of developing a better insight into the TB/HIV co-epidemic. Undeniably, diagnosing persons who are HIV infected is a prerequisite to the provision of treatment, care and support, but there is evidence that many opportunities are being missed to diagnose HIV and TB infections in EU, particularly among most-at-risk groups.

Case reporting data show that between 2000 and 2007 the annual rate of HIV infection in EU has almost doubled, from 39 to 75 per million populations. This general data considerably understates the true figure because a large proportion of HIV infected persons – ranging from an estimated 15% to over 50% in EU – are unaware of their infection, and therefore do not benefit from treatment and may transmit HIV to others, unknowingly. Late diagnosis represents a public health challenge, since it increases risk of morbidity and mortality, risk of more opportunistic infections, such as tuberculosis, risk of onward transmission. The proportion of TB cases with positive HIV serostatus in EU range from 2% to 15%. At this regard, the WHO recommends to develop a better insight into the TB/HIV co-epidemic and enhancing surveillance of TB among vulnerable populations. Immigrants from resource constrained settings have incidence rates of TB 10 to 30 times higher than those recorded in Europe. This is why this disease is re-emerging as an important challenge to public health in Europe.

Studies show that testing high risk patients for TB and HIV may favour timely identification of these infections and timely access to care. In Netherland, as a response to a doubling of TB cases among illicit drug users and homeless persons a comprehensive targeted screening program was introduced in 2002. Three years and 8 months after the introduction of periodic mobile screening, the annual number of TB cases among illicit drug users and homeless persons, and their proportion of the total number of TB cases, had declined by approximately 50% and reached pre-out-break incidence level.

The approach needed to increase effective testing of DUs and migrants DUs is to consider the specific needs of these target groups and combine testing offer with low-threshold drug services, as indicated in all main existing testing guidelines. Indeed, the main reason for which many DUs and migrants DUs have never been tested is the lack of contacts of these target groups with the care system, due to their marginalized life styles and their mistrust in the health services.

Harm reduction programmes and low-threshold facilities are recognized as important points for entering into contact with "hidden" and "hard-to-reach" populations of drug users, and are considered essential for delivering basic health and social care. The availability of testing in street units and drop-in centres will offer to drug users, including migrants DUs, an easy possibility to be tested without the need of going to specific health services.

Moreover, there is a need for standardised reporting and analysis of new HIV and TB diagnoses among these groups and for developing specific indicators to monitor stigma and access to testing and care. A standardised data collection system will contribute to obtain a reliable overview of the trends of the two epidemics at national and subsequently, at European level and a more rigorous evaluation of case detection and treatment outcomes of TB and HIV patients.

2. OBJECTIVES

1. To develop a framework and model to improve the effectiveness of HIV and TB testing and counselling among DUs and migrants DUs, based on a new kind of provider-initiated counselling and testing, specifically tailored to hard-to-reach groups.
2. To increase the percentage of DUs and migrants DUs having access to HIV and TB testing, promoting early recognition of HIV and TB disease and timely entry into care.
3. To facilitate access to treatment and care for most marginalized and risk groups, promoting a close cooperation among organizations working with drug users and public health care services.
4. To promote healthier ways of life and risk reduction among drug users and migrants DUs, through pre and post counselling and easier access to health centres.
5. To assess the effectiveness of street HIV and TB testing in terms of proportion of new infection identified.

2.1 Specific research questions

1. What is the percentage of early identification of new cases of HIV and TB and timely entry into care?
2. What are the main determinants that contribute to a late or early diagnosis and enrolling into care, treatment, prevention and support services?
3. What are the barriers to access HIV and TB testing, care and treatment?
4. Which legal frameworks (laws, regulations) create main additional barriers?
5. What are the main risk behaviours for HIV and TB among these two target groups?

3. METHODS

3.1 Study design

The project consists of three phases:

1. Development of common tools for street HIV and TB testing among PDUs. Methods and means:

a) Organization of workshops/seminars in order to (1) exchange experience and information among the project partners, and (2) analyze weaknesses and challenges of current HIV and TB testing strategies.

b) Development of training courses for multi-disciplinary staff (doctors, social workers, psychologists) working in low-threshold services for PDUs.

c) Identification of specific indicators/determinants for monitoring and reporting of new diagnosis among these target groups.

2. Implementation of HIV and TB rapid tests in low-threshold facilities for PDUs. Methods and means:

a) Training courses for the staff of the partner organizations in the four different locations.
b) Data collection: clients are requested to fill in a questionnaire for collecting data on lifestyles, behaviours, health conditions, history of HIV and TB testing. All these data will be entered in an online database and analysed.
c) Actual implementation: provision of testing (among 700 and 1000 HIV TB tests per city), counselling and referral to clinical centres for confirmation of results and treatment.
d) Follow-up: A follow-up appointment will be scheduled at dedicated health care services for confirmatory diagnosis of those individuals that result HIV-reactive and TB positive.
e) Treatment: All collaborating clinics offer HIV and TB treatment therapy. Within this project only treatment entry will be measured, since the project period is too short to effectively measure adherence.

3. Analysis and assessment of effectiveness of the intervention, as well as dissemination of the results. Methods and means:

a) Analysis of all collected demographical, epidemiological, clinical and laboratory data from each partner (number of persons tested, number of HIV and TB-positive, number of persons received treatment after testing).
b) Assessment of short-term impact of the intervention (as far as this is possible within the current set-up without control group and without quantitative pre-intervention measurement).
c) Publication of guidelines for best practices dissemination.
d) Organization of a final conference for presenting project results and outcomes.

3.2 Implementation of HIV and TB rapid testing in low-threshold facilities for DUs

Before starting the testing uptake, each organization will conduct a *training course* for its own team, using the manual jointly developed by all the partners. The project staff will be composed by psychologists, doctors, social and outreach workers, for an average number of 15 persons per partner. Training will address the following key areas: ensuring an ethical process for obtaining informed consent, protection of confidentiality and privacy, conduction of pre and post counselling, conduction of focus group and questionnaire among the target groups for data collection, testing provision, patient referral to treatment services. Representatives of the collaborating partners (clinical health centres) will also participate at the training; this will offer an opportunity to raise awareness about stigma and discrimination frequently reported in health-care services toward drug users and migrants, in order to reinforce their adherence to appropriate standards of practice.

The trained staff will then carry out HIV and TB tests among PDUs (problematic drug users, including migrants) attending low-threshold services managed by each partner organization. The team will be composed by doctors or nurses (for testing uptake), psychologists and outreach workers (for pre and post-counselling, data collection and referral to health centres).

The target groups will be provided with *information leaflets* on HIV and TB infection, the aim of the project, the procedures of testing, the aspect of anonymity and privacy. Those accepting to be tested will be asked to give the *informed consent* (written or verbal, according to the local rules) and will be offered HIV rapid test (DETERMINE HIV 1-2) and a clinical screening for TB.

Before the testing, *pre-counselling* will be provided by a counsellor in the form of individual talks. The pre-counselling will include the following information: reasons why HIV and TB testing and counselling is being recommended; clinical and prevention benefits of HIV and TB testing and the potential risks; services available in case of either an HIV/TB-negative or an HIV-reactive and

TB positive test result; confidentiality of the test and respect of privacy in the treatment of test result; right of the patient to decline the test; encouragement of disclosure to other persons who may be at risk of exposure to HIV and TB, in case of an HIV-reactive or TB positive test result.

During the pre-test counselling or while waiting for the HIV rapid test result, a *questionnaire* will be administered to the client, in order to collect data on lifestyles behaviours, health conditions and history of HIV and TB testing.

All individuals undergoing the testing will receive *post-test counselling*, regardless of the test result. For those with reactive HIV results, a follow-up appointment will be scheduled at dedicated health care services for confirmatory blood test.

As for TB, a *clinical screening* will be conducted by the project staff in order to identify suspected cases with TB symptoms (prolonged cough, fever, chest pain, breathlessness, loss of weight, fatigue).

From those individuals with one or more clinical symptoms or with other risk factors (HIV-positivity, contacts with TB infected patients, etc) a *sputum sample* will be collected and sent to clinical centres for analysis. The sputum sample will be handled with care in order to avoid any risk of infection for the staff, so the patient himself will spit the sputum sample in a sterile container following the instructions of the staff.

In case of positive result, the staff will arrange a follow-up appointment to the clinical centres for the collection of a second sputum sample and further diagnostic workup for TB, according to WHO suggested protocols.

In case of negative result, a second sputum sample will be collected as soon as possible and only in case of positive result the client will be referred to the clinical centres.

As for the project partner SANANIM, since the national legislation obliges service providers to refer immediately any suspected case of infectious disease to specialized health centre, they will conduct the clinical screening in their centre and then, will accompany the suspected cases directly to specialized health facility for further examination (X-ray and sputum examination).

The identified HIV and TB positive cases will receive the most appropriate treatment for HIV and therapy for TB in the clinical services involved in the project as collaborating partners. Specific agreement (written or verbal) will be made between each partner organization and its collaborating partners, in order to facilitate access to treatment to the project target groups.

Moreover, the staff will arrange specific follow-up visits or referrals to other services as appropriate (STI treatment, family planning, antenatal care, opiates substitution therapy).

4. STUDY POPULATION

The project target two specific groups: drug users and migrants drug users living in Rome, Turin, Prague and Bratislava. With the term drug users we intend "*problem drug users*" according to the definition of EMCDDA: "Problem drug use is defined as injecting drug use or long-duration/regular use of opioids, cocaine and/or amphetamines". Taking into account the fact that at the moment other substances are mostly used among the selected target group, also people that use benzodiazepines will be considered eligible for the project.

Migrants are defined as first generation migrants independent of their nationality, including both illegal and legal migrants.

Inclusion criteria

Participants will be eligible for screening when they meet all of the following criteria:

– Problem DUs, clients of the low-threshold facilities managed by the leader and partner organizations.

– Being over 18 years of age.

– Able to understand the study goal, purpose and procedures involved.
– Having given their informed consent.

Exclusion criteria

Participants will be excluded from screening when one of the following applies:

– Being under 18 years of age.
– Not understanding the study's purpose and procedures and therefore unable to give informed consent (because under the effects of drugs or for language barriers).
– HIV positive (only for HIV rapid test).
– Being tested for HIV in the last 3 months.

4.1 Recruitment

The selected groups will be recruited among drug users and migrant drug users attending low-threshold services (drop-in centres, needle-exchange points, street units) managed by the partner organizations in the above mentioned four European cities.

The clients of these services will be firstly approached by the outreach and social workers, who will offer them the possibility to be tested for HIV and TB. The selection and approach of the target groups will be completely random.

All the people approached, including both those willing and those unwilling to participate at the testing, will be recorded in a *Response Monitoring Form* which will include the gender, age, country of origin and reason for refusal.

Those accepting to be tested will be asked to give the *Informed Consent* (written or verbal, according to national rules), after having read the *Informative leaflets* on HIV and TB with clear explanation of the procedure for testing and the respect of anonymity and confidentiality.

If they are unable to understand the consent form and the objectives of the intervention, they will be excluded by the study.

4.2 Sample size

Each partner organization will conduct from 700 to 1.000 HIV tests and 1.000 TB screening/tests. This number has been estimated according to the time required for conducting pre and post counselling and test uptake (around 20-25 HIV tests and 20-25 TB tests per week, for an average total number of 1000 tests per year).

The indicated sample size is intended as contacts and not as single individuals, because participants with high risk behaviours for HIV may be re-tested after 3 months. This means that the number of individuals being tested will range from a minimum of 250 to a maximum of 1000 per each city.

5. STUDY PROCEDURES AND ASSESSMENT

5.1 Data definition

Data that need to be collected within the project serve to give a baseline measurement which can be compared with a post-intervention measurement and show behavioural change and changes in experiences among the target groups.

The data collected will be both quantitative and qualitative.

Quantitative

– number of people tested for HIV and TB,
– number of HIV and TB positive cases detected,
– number of early infections detected,
– number of positive persons receiving treatment after testing,

Qualitative

– experienced access to HIV and TB testing,

– experienced access to confirmatory diagnosis and treatment of HIV and TB,

– experienced effectiveness of outreach based HIV and TB testing, rate of use of safe lifestyles and preventive measures regarding HIV and TB.

Main Outcome measures

– Number of PDUs and migrant DUs tested for HIV and TB once or more in the last year and proportion of notified TB and HIV cases among those unaware.

– Proportion of HIV and TB positive individuals receiving treatment and care for these two diseases.

– Percentage of PDUs and migrant DUs among those eligible who adopt safer lifestyles and HIV and TB preventive measures.

– Assessment of key determinants of late presentation for testing and care and the ones of timely diagnosis and entry into care for these two risk groups.

5.2 Data collection

At the beginning of the intervention, demographical, epidemiological and clinical data on the target groups will be collected, in order to have a basic overview of local characteristics of target groups and services available in all the cities involved in the project.

This data will be collected through:

– review of official epidemiological data on drug use, HIV and TB infection;
– interviews with selected experts/key-informants;
– focus groups with target group members.

Before the start of the intervention, *2 focus groups* with target group members will be conducted in each of the participating countries, in order to collect baseline information on risk behaviours for HIV and TB, testing behaviours, access to testing, care and treatment. At the end of the intervention, other *2 focus groups* will be conducted in each city, and the information collected represent the post-intervention measurement to be compared with the baseline one.

During the implementation phase, additional demographical, epidemiological and behavioural data on the target groups will be collected through a *questionnaire*, that will be administered to the people tested while waiting for the test results or after the screening.

This data include information about lifestyles, risk behaviours, health conditions, history of HIV and TB testing, access to health-care services, as well as personal data such as education level, relationship status, employment, housing condition.

In case all participants take only one test per year, 4.000 questionnaires will be collected. However, if a large part of participants gets retested within the project, the number of collected data files will decrease.

5.3 Data handling

Each client will be recorded with a personal *barcode*, which will be indicated on the following items:

1) Informed consent form.
2) Questionnaire for data collection.
3) HIV rapid test.
4) Clinical screening form/ Container for sputum sample.
5) Referral paper for the clinical centre, in case of reactive test result.

Moreover, each individual will be registered manually on a separate file with a personal code (for example name/nickname and date of birth), according to the coding system normally used by each organization. This will allow clients to know their own codes and will facilitate the identification of those individuals who may lost their barcode, since the result of sputum smear is not immediate.

All data of the persons enrolled in the project will be stored anonymously in a structured database using a single entry.

Data on actual attendance to clinical centres by patients referred there by the participating organizations will be collected by the clinical centres. For those found HIV positive by rapid test, data on confirmatory testing, clinical evaluation and laboratory evaluation (CD4 cells count and HIV RNA) will be collected.

For those found positive at TB symptoms screening, data on results of sputum laboratory examination and final diagnosis will be collected.

6. ETHICAL CONSIDERATIONS

A number of organizational procedures will be followed to ensure the respect of privacy, confidentiality, and security during collection, storage, use, dissemination, and disposal of personal identified data and other information, according to the main international guidelines.

The testing will be conducted only after obtaining informed consent of subjects, in line with the national legislation of all participating countries and with the UNAIDS/WHO Policy statement on HIV testing. Informed consent will be given individually, in presence of a trained health care provider (WHO Guidance on provider-initiated HIV testing and counselling in health facilities).

The questionnaires and the tests will be identified with a barcode, in order to respect anonymity. The informed consent forms and the questionnaires will be accurately stored in the offices of each partner organization.

Moreover, for ensuring the respect of all ethical and privacy protection principles, each partner organization will ask for the approval of the ethical committee of its own country, according to the legislation and procedures in force in each country.

7. PROJECT MANAGEMENT

The organization involved in the project are Villa Maraini Foundation (Rome), Gruppo Abele (Turin), Foundation Regenboog Groep (Amsterdam), SANANIM (Prague), Odyseus (Bratislava).

Except the Foundation Regenboog Groep, which will be in charge of the overall project evaluation and assessment of the outcomes of the intervention, all the listed organizations will conduct the HIV and TB testing among DUs and migrant DUs in low-threshold services.

Moreover, each organization will involve in the project as collaborating partner the following clinical institute for treatment and care of infectious diseases:

- National Institute of infectious diseases “Lazzaro Spallanzani” in Rome.
- Hospital for infectious diseases “Amedeo di Savoia” in Turin.
- Klinika infektologie a geografickej mediciny FNsP Bratislava a LF UK in Bratislava.
- AIDS centrum FN Bulovka and Azylové centrum Ceské spolecnosti AIDS pomoc in Prague and specific health facility specialized in TB screening.

These institutes will act as the clinical reference centres of the project, providing all required examinations and treatment for HIV and TB to those individuals referred there by the partner organizations.

The overall project coordination will be conducted by the administrative staff that Villa Maraini will enrol in the project: the project coordinator, the administrative assistant and the financial manager.

Moreover, during the Kick-off Meeting a Steering Committee with representatives of all the partners will be set up. This Committee will be responsible for ensuring coordination among all the organizations involved and respect of tasks and obligations of each partners, as defined in the Working Plan.

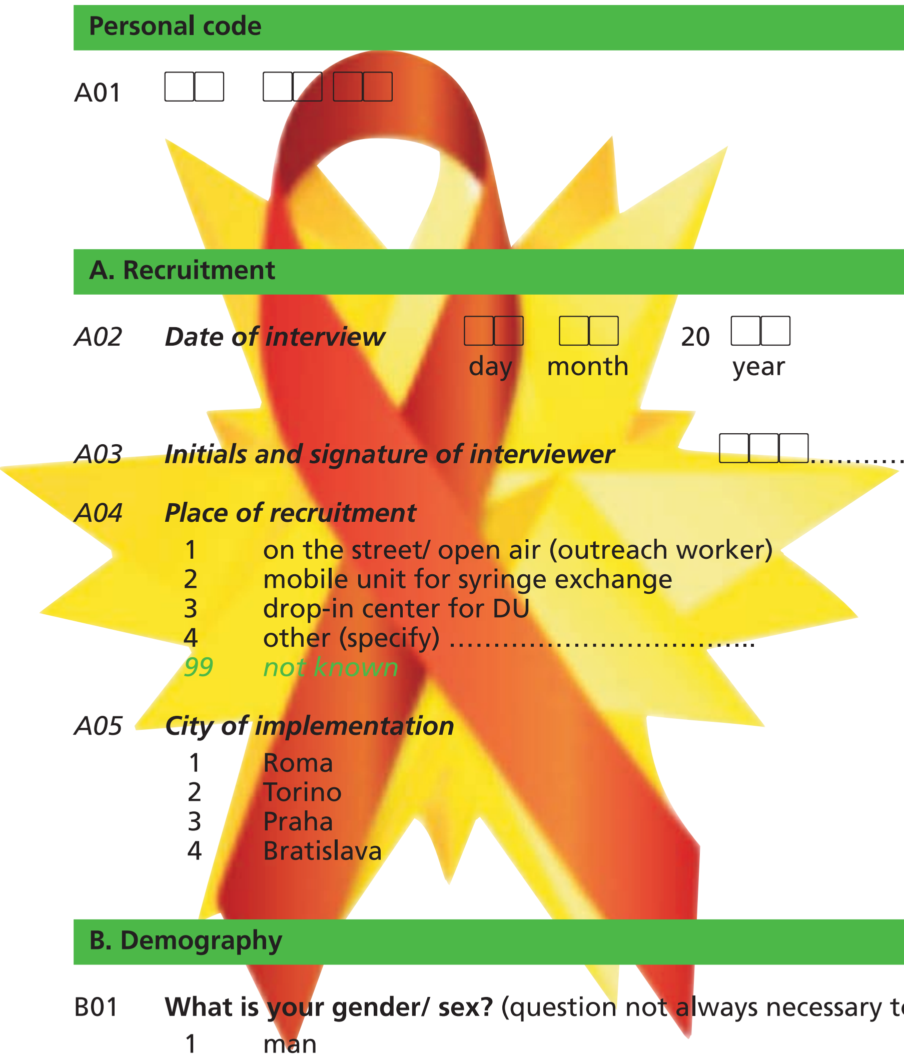
The coordination activities among the project leader and the partners will be constant, through regular exchange of email, telephone calls, fax.

Moreover, the partners will have the possibility to meet and discuss project issues during all the meetings which will be organized within the project: Kick-off Meeting, 1st and 2nd Workshop on HIV/TB testing, 1st and 2nd Experience-Sharing Meeting, Final Conference.

All the methods and tools to be used for the study will be jointly developed by all the organizations during these project meetings.

In addition to this, in order for the main partner to better coordinate all the project activities, every three months each partner will submit to Villa Maraini and FRG (the partner organization in charge of the evaluation) a technical report of the implemented activities and a financial statement of incurred expenses. These reports will serve to identify possible problems and jointly find corrective action.

Annex II
The questionnaire for data collection



Personal code

A01 ☐☐ ☐☐☐☐

for Rome: from RM0001 to RM1000
for Turin: from TO0001 to TO1000
for Praga from: CZ0001 to CZ1000
for Bratislava from: SK0001 to SK1000

A. Recruitment

A02 ***Date of interview*** ☐☐ day ☐☐ month 20 ☐☐ year

A03 ***Initials and signature of interviewer*** ☐☐☐...................................

A04 ***Place of recruitment***

1 on the street/ open air (outreach worker)
2 mobile unit for syringe exchange
3 drop-in center for DU
4 other (specify) ....
99 not known

A05 ***City of implementation***

1 Roma
2 Torino
3 Praha
4 Bratislava

B. Demography

B01 **What is your gender/ sex?** (question not always necessary to ask)

1 man
2 woman
3 transsexual / transgender

B02a **What is your month and year of birth?**

☐☐ ☐☐☐☐
day month

In case respondent does not know, ask him/her to estimate year of birth don't know= 99, refuse = 88

B02b ***Interviewer: Participant is sure about this, or is it an estimation?***

1. sure
2. estimation

B03 **In which city do you currently live?**

1 Prague/ Bratislava/ Rome/ Turin
2 other (say where)...........................
88 refusal
99 don't know

B04 **Which housing situation best describes yours (in the last 12 months, most of the time)?**

1 stable accommodation (owning, renting or staying with family/ friends for unrestricted time)
2 unstable accommodation (living in a hostel/shelter without a steady address, or on the streets)
3 in institutions (prison, clinic)
4 other, specify: ……………………………………………..
88 refusal
99 don't know

B05 **Have you been homeless in the last 12 months, that means: staying on the streets or in a hostel without a steady address for one week or longer?**

1 No
2 Yes
88 refusal
99 don't know

B06 **With whom are you living (most of the time), at the moment?**

1 alone
2 with parents
3 with child(ren) alone
4 with partner alone
5 with partner and child(ren)
6 with friends
7 other, specify: ……………………………………………
88 refusal
99 don't know

B07 **In what country were you born?**

1 CR/ Slovakia/ Italy → *go to question B10*
2 Other, say where (country):
88 refusal
99 don't know

B08 **How long have you been living in CR/ Slovakia/ Italy?**

☐☐ years

if shorter than 6 months, answer is 0

B09 **Do you have all the necessary documents and papers to live and work/study in this country?**

1 No
2 Yes
88 refusal
99 don't know

B10 **Are there any specific ethnic groups that you feel you belong to?** *[e.g., Roma, Sinti?]*

1 No
2 Yes, specify: …………………………………
88 refusal
99 don't know

B11 **What is the highest level of education that you completed?**

1 never went to school/ never completed primary school
2 primary level of education
3 secondary level of education
4 higher education
5 other, specify: ………………………………
88 refusal
99 don't know

B12 **What is your current job status?**

1 regular employment

2 pupil/ student
3 economically inactive (pensioners/ housewives, -men/ invalids)
4 unemployed
5 undeclared/unofficial work
6 other, specify:……………………………….
88 refusal
99 don't know

C. Drugs

C01 **How old were you when you started using drugs - we are talking about injecting drug use or regular use of opioids, cocaine, amphetamines and/or benzodiazepines. Regularly means 1 day per week or more.**

☐☐ years old *don't know = 99, refuse = 88*
never used regularly = 00

note for translator/ programmer: order C02-C04 changed, also the reference 'go to question…'has changed

C02 **Have you injected in the *last 4 weeks?***
Persist with questioning, watch out for socially acceptable answers.

1 no
2 yes → *go to question C05*
88 refusal
99 don't know

C03 **Have you injected in the *last 12 months?***

1 no
2 yes → *go to question C05*
88 refusal
99 don't know

C04 **Have you *ever* injected drugs?**

1 no
2 yes
88 refusal
99 don't know

C05a **What drugs have you used in the *last 4 weeks?***
Read out all options. More than one option is possible.

C05b **Which drugs you just mentioned have you also injected *in the last 4 weeks*?**
Persist with questioning about injecting because of the possibility of lying or giving socially acceptable answers.

C05a Used	**C05b Injected**	
01	01	heroin alone *(if in fact Fentanyl, put under 6)*
02	02	cocaine alone
03	03	heroin and cocaine together
04	04	heroin and metamphetamines (pervitin) together
05	05	refined coke (freebase, crack, etc. *if refined at home, put under 2 not here*)
06	06	Fentanyl ('fake' heroin)
07	07	methadone
08	08	buprenorphine (subutex/ subuxon)
09	09	other opiates (palfium, morphine, opium, burgadin, etc.)
10	10	amphetamines (speed)
11	11	methamphetamines (pervitin)
12	12	benzodiazepines
13	13	ecstasy

14	14	ketamine
15	15	GHB/GBL
16	16	'pills', please specify:..
17	17	cannabis (hashish / marihuana)
18	18	alcohol ('using alcohol' = more than 4 glasses per day)
19	19	other substance, please specify:..

NOTE for translator/ programmer: numbers have changed

If respondent has NOT ever injected (C04=1) → go to section D

C06 **Have you *ever* injected *with a used syringe or needle* from someone else?**
Persist with questioning, watch out for socially acceptable answers.

1 no → *go to C10*
2 yes
88 refusal → go to C10
99 don't know → go to C10

C07 **With what frequency did you inject with a *used* syringe or needle from someone else, in the last 12 months?**

1 never
2 occasionally
3 about half the time
4 mostly
5 always
88 refusal
99 don't know

C08 **Have you injected with a used syringe or needle from someone else, *in the last four weeks*?**

1 no
2 yes
88 refusal
99 don't know

C09 **Thinking about the last time you borrowed a used syringe or needle, what was the *most important* reason?**
Do not read out! *Keep asking, but only* one *answer possible*. *If respondent says: 'I did not have a clean one', ask further: 'What was the reason that you did not have a clean one, or could not get a clean one?' Tick the most appropriate answer.*

1 too far from needle exchange / machine
2 needle exchange not open
3 needle exchange machine broken
4 someone else did the shot for me
5 unplanned shot, so no syringes available
6 withdrawal symptoms (ill) so wanted to inject as quickly as possible
7 I didn't care (indifference)
8 sharing with partner
9 other (give details) ………………………………..
88 refusal
99 don't know

C10 **Have you *ever* borrowed any cotton, wool, filter, spoon, flushing water or other items that had been used by someone else?**

1 no → *go to section D*
2 yes
88 refusal → go to section D
99 don't know → go to section D

C11 **Have you borrowed any cotton, wool, filter, spoon, flushing water or other items that had been used by someone else, *in the last four weeks*?**

1 no
2 yes
88 refusal
99 don't know

D. Prison

D01 **Have you ever been in prison? (**Do *not include police cells or 'migrant identification centres',* but *do include all other forms* of detention, such as pre-trial detention, prison, etc)

1 no *→ go to section E*
2 yes
88 refusal → go to section E
99 don't know → go to section E

Now I'd like to ask you some questions about your time in prison.

D02 **Since you started using, how often have you been in prison?** (Don't count police cells.)

☐☐ times *don't know = 999; refuse = 888*
never = 0

D03 **Have you ever injected drugs in prison?**

1 no
2 yes
88 refusal
99 don't know

D04 **The last time you were in prison, how many people were with you in the cell?** (at the most)
This is to assess risk for TB. In case the cell was in some periods shared and in some periods not shared, do not write 0, even if this was mostly the case. Choose the maximum amount of people that he/she shared a cell with. If not sure, estimate.

☐☐ persons

E. Sexual partners

I'm now going to ask you some questions on the sexual partners you've had.

- **The questions might *be private* so please let me know if you feel uncomfortable discussing this with me. As I said before, what you tell me, will remain within these 4 walls (so to speak). I hope that you understand that we need to ask these questions, to assess some kind of risk behaviours. If you *really* do not wish to answer, you can always refuse to answer a question.**
- **All the questions in this section *concern the last 12 months*.**
- **With *sexual intercourse or sex we mean vaginal or anal intercourse only* (no oral sex or handjobs).**
- ***NTERVIEWER: you may say either 'sex' or 'sexual intercourse', as you prefer. The vaginal/anal part does not have to be mentioned, unless participant has forgotten. The 'last 12 months' part is often forgotten, so keep reminding the participant if necessary.***

E01 **Have you had any sexual intercourse in the last 12 months?**

1 no *→ go to section F*
2 yes
88 refusal → go to section F
99 don't know

E02 **Now we will ask you some questions about sex with one or more stable partners in the last 12 months. Have you had sexual intercourse with one or more *stable* sexual partner in this period?**
(do not include casual partners or sex in change for money, drugs or other benefits)

1 no *→ go to question E05*
2 yes
88 refusal → go to question E05
99 don't know → go to question E05

E03 **How often did you and your stable partner(s) use a condom during sex (in the last 12 months)?**
(do not include casual partners or sex in change for money, drugs or other benefits)

1 never
2 occasionally
3 about half the time
4 mostly
5 always
88 refusal
99 don't know

E04 **To your knowledge has/have this/these stable partner (s) *ever* injected drugs?** (not only last 12 months!)
(do not include sex in change for money, drugs or other benefits)

1 no
2 yes
88 refusal
99 don't know

E05 **Now we will ask you some questions about sex with casual sexual partners. Have you had sexual intercourse with one or more *casual* sexual partners in the last 12 months?**
(*do not include sex in change for money, drugs or other benefits)*
1 no → *go to question E09*
2 yes
88 refusal → go to question E09
99 don't know → go to question E09

E06 **With how many *casual partners* have you had sexual intercourse in the last 12 months?**
(do not include sex in change for money, drugs or other benefits)

☐☐ people *don't know = 999; refuse = 888*
none = 0

E07 **How often did you and your *casual partner(s)* use a condom during sex in the last 12 months?**
(do not include sex in change for money, drugs or other benefits)
1 never
2 occasionally
3 about half the time
4 mostly
5 always
88 refusal
99 don't know

E08 **To your knowledge has your casual partner(s) ever injected drugs?**
(not only last 12 months!)
1 no
2 yes
88 refusal
99 don't know

E09 **During the last 12 months have you had sexual intercourse with *people who paid you* with money, drugs or other benefits for the sex ('clients')?**
1 no → *go to question E12*
2 yes
88 refusal → go to question E12
99 don't know → go to question E12

E10 **With how many 'clients' have you had sexual intercourse *in the last 12 months*?**

E10a) ☐☐☐ Sexual contacts
don't know = 999; refuse = 888
E10b) *none = 0*
1 per week
2 per month
3 for the whole year

E11 **How often did you use condoms during sexual intercourse *with these 'clients' in the last 12 months*?** (Take the average for all clients). *Persist with questioning because of the risk of socially acceptable answers!*

1	never
2	occasionally
3	about half the time
4	mostly
5	always
88	*refusal*
99	*don't know*

E12 **During the *last 12 months, have you paid* with money, drugs or other benefits for sexual intercourse with people?**
(This means that you were the client)

1	no → *go to question E15*
2	yes
88	*refusal → go to question E15*
99	*don't know → go to question E15*

E13 **How many people in the last 12 months did you pay to have sexual intercourse with you?**
(This means that you were the client)

E13a) ☐☐☐ Sexual contacts
don't know = 999; refuse = 888
E13b) *none = 0*

1	per week
2	per month
3	for the whole year

E14 **How often did you use condoms during these types of sexual contacts in *the last 12 months*?**
(Take the average for all contacts with sex workers)

1	never
2	occasionally
3	about half the time
4	mostly
5	always
88	*refusal*
99	*don't know*

E15 **Have you been diagnosed with sexually transmitted diseases (STD's) like syphilis, gonorrhea, herpes, chlamydia, genital warts or any other sexually transmitted infections in the *past 12 months*?**

1	no
2	yes
88	*refusal*
99	*don't know*

F. HIV testing

F01 **Have you ever done an HIV test?**

1	no → *go to question F04*
2	yes
88	*refusal → go to question F04*
99	*don't know → go to question F04*

F02 **When did you last have a HIV test?** (try to estimate at least the year if uncertain date)

☐☐ ☐☐☐☐ *don't know = 9999; refuse = 8888*
month year

F03 **What was the result of that test?**
(If several tests, give result of the last one)

1 negative
2 positive
3 I never got the result
88 refusal
99 don't know

Go to section G if participant has been tested for HIV before.
Only complete remainder of section F if F01=1, 88 or 99 (not been tested)

F04 **Have you ever been offered an HIV Test before (and not taken it)?**

1 no → *go to Question F06*
2 yes
88 refusa → go to Question F06
99 don't know → go to Question F06

F05 **If yes, by which organisation?**

1 public health service, specify………………………
2 service for drug users, specify……………………..
3 other service, specify: ……………………………
88 refusal
99 don't know

F06 **You have never been tested for HIV before. What was the reason for this or what were the reasons for this?**
IMPORTANT!!* DO NOT READ OUT *options, but let respondent explain, and tick the most appropriate answer(s). Do NOT mention possible reasons, but ask 'anything else?'
(more than 1 answer possible)

1 I don't think I am infected
2 I'm afraid to do the test, because I could be infected
3 I don't feel comfortable to go to the clinic, *because I use drugs*
4 I don't feel comfortable to go to the clinic, *because I am (undocumented) migrant*
5 I don't feel comfortable to go to the clinic, *because I am doing illegal things (other than DU)*
6 I have no health insurance
7 It is not something that I think of, I have other priorities (e.g. getting drugs)
8 I always wanted to get a test, but never got round to it
9 It is too much of a hassle
10 other (specify)..

F07 **What made you decide to have the test now?**
IMPORTANT!! Do not read out options, but let respondent explain, and tick the most appropriate answer(s). Do NOT mention possible reasons, but ask 'anything else?'
(more than 1 answer possible)

1 The test was offered to me, I did not have to go after it myself
2 The test is free of charge (even if I don't have health insurance)
3 I will receive a reward for taking part in the study
4 The results will be given immediately, I do not have to come back
5 I am not really interested in the HIV test, more in the TB test
6 I think I could be infected
7 I feel more comfortable to do the test in this (familiar) setting
8 I feel more comfortable to have the test here, because the fact that I use drugs is not a problem
9 I feel more comfortable to have the test here, because the fact that I am (undocumented) migrant is not a problem
10 I feel more comfortable to have the test here, because the fact that I am doing illegal things (other than DU) is not a problem
11 other (specify)...

G. TB testing

These questions are about the TB test.

G01 **Have you ever been vaccinated for TB?**
Make sure that participant does not confuse vaccination with Mantoux skin test

1 no
2 yes
88 refusal
99 don't know

G02 **Have you ever been tested for TB?**

1 no → *go to Question G06*
2 yes
88 refusal → go to Question G06
99 don't know → go to Question G06

G03 **When did you last have a TB test?** (try to estimate at least the year if uncertain date)

☐☐ ☐☐☐☐ *don't know = 9999; refuse = 8888*
month year

G04 **Which kind of test or tests did you have?** *If necessary, explain testing methods*
(more than one answer possible)

1 thorax (chest x-ray)
2 sputum
3 skin test (mantoux)
4 blood test
5 other (specify):……………………………..
88 refusal
99 don't know

G05 **What was the result of the test or tests?**
(If several tests, give result of the last one)

1 negative
2 positive
3 I never got the result
88 refusal
99 don't know

Go to section H if participant has been tested for TB before.
Only complete remainder of section G if G02=1, 88 or 99 (not been tested)

G06 **Have you ever been offered a TB Test before?**

1 no → *go to Question G08*
2 yes
88 refusal → go to Question G08
99 don't know → go to Question G08

G07 **If yes, by which organisation?**

1 public health service, specify….
2 service for drug users, specify….
3 other service, specify: ……………………………
88 refusal
99 don't know

G08 **You have never been tested for TB before. What was the reason for this or what were the reasons for this?**
IMPORTANT!! **Do** not ***read out options, but let respondent explain, and tick the most appropriate answer(s). Do NOT mention possible reasons, but ask 'anything else?'***
(more than 1 answer possible)

1 I don’t think I am infected
2 I’m afraid to do the test, because I could be infected
3 I don’t feel comfortable to go to the clinic, because I use drugs
4 I don’t feel comfortable to go to the clinic, because I am (undocumented) migrant
5 I don’t feel comfortable to go to the clinic, because I am doing illegal things (other than DU)
6 I have no health insurance
7 It is not something that I think of, I have other priorities (e.g. getting drugs)
8 I always wanted to get a test, but never got round to it
9 It is too much of a hassle
10 other (specify)..

G09 **What made you decide to have the test now?**
IMPORTANT!! Do **not** ***read out options, but let respondent explain, and tick the most appropriate answer(s). Do NOT mention possible reasons, but ask ‘anything else?’***
(more than 1 answer possible)

1 The test was offered to me, I did not have to go after it myself
2 The test is free of charge (even if I don’t have health insurance)
3 I will receive a reward for taking part in the study
4 The results will be given immediately, I do not have to come back
5 I am not really interested in the TB test, more in the HIV test
6 I think I could be infected
7 I feel more comfortable to do the test in this (familiar) setting
8 I feel more comfortable to have the test here, because the fact that I use drugs is not a problem
9 I feel more comfortable to have the test here, because the fact that I am (undocumented) migrant is not a problem
10 I feel more comfortable to have the test here, because the fact that I am doing illegal things (other than DU) is not a problem
11 other (specify)..

H. Remarks

H01 **Would you like to add any remarks or additional information that might be relevant to this study?**

1 No
1 Yes, specify:
....
....

Thank you for taking part!

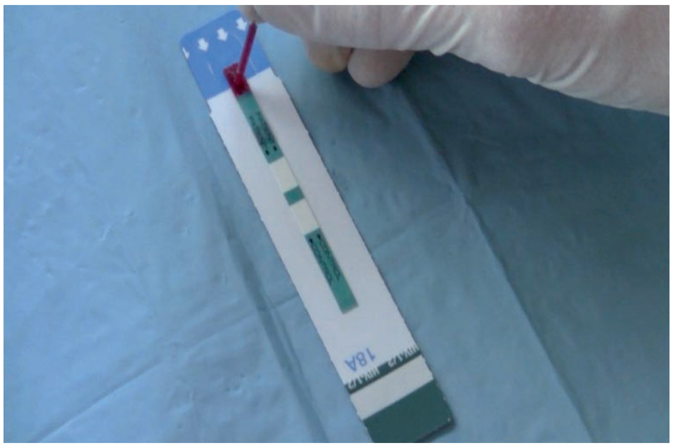
I. Remarks interviewer

I01 **Would you as an interviewer like to add any remarks that might be relevant for the interpretation of this respondents information?**

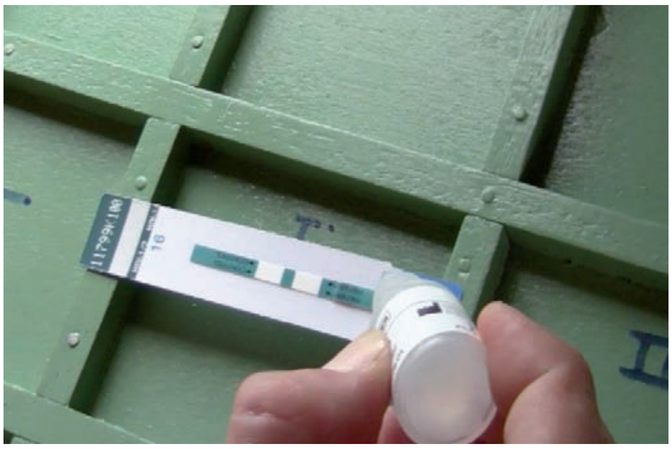
1 No
2 Yes, specify:
....
....

Mobile units in Rome

Blood collection by finger stick



HIV rapid test



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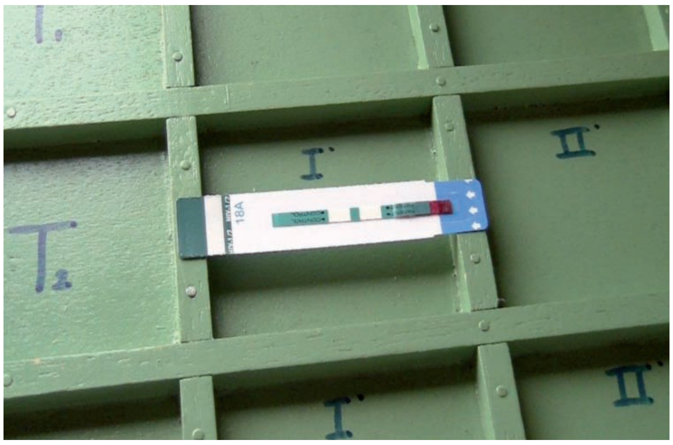

Waiting for test results