RISK ASSESSMENT GUIDELINE

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LOCAL PASS

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INTRODUCTION

The current document describes a schematic representation for a local system of (Rapid) Risk Assessment of new trends in psychoactive substance use on the local level ("Risk Assessment" or "RA process"). Risk Assessment is the second of three consecutive components in a model of Identification, Risk Assessment & Intervention ("IRI"-model), as described in the Local PASS Toolkit Guideline. It should be used in conjunction with the other two components, as described in the Identification Guideline and the Intervention Guideline

This Risk Assessment Guideline is structured as follows. First, the aims of the local Risk Assessment procedure are presented in Chapter I. Then, the schematic representation of the RA process is given in Chapter II. In Chapter III, we describe the procedures of Rapid Assessment and Risk Assessment on the local level, and the bodies responsible for their performance. Finally, we present the tools of the Risk Assessment process in Chapter IV –the Data Evaluation score sheet and the Final Assessment recommendations for interventions, using the Risk Evaluation Checklist and Score Sheet (see Figure 2).

I. RISK ASSESSMENT: AIMS

Risk Assessment is one of a set of three inseparable components performed by the Local Emerging Drug Trends Panel (see the Local PASS Toolkit Guideline). A schematic depiction of the local Risk Assessment process is presented in Figure 1. The aims of the Risk Assessment process are to:

- collect relevant available data about risks of new trends in substance use on the local level,
- assess the relevance of the available data and to evaluate them,
- inform drug policy decision making on the local level,
- provide data necessary for implementing or designing appropriate responses to the new trends.

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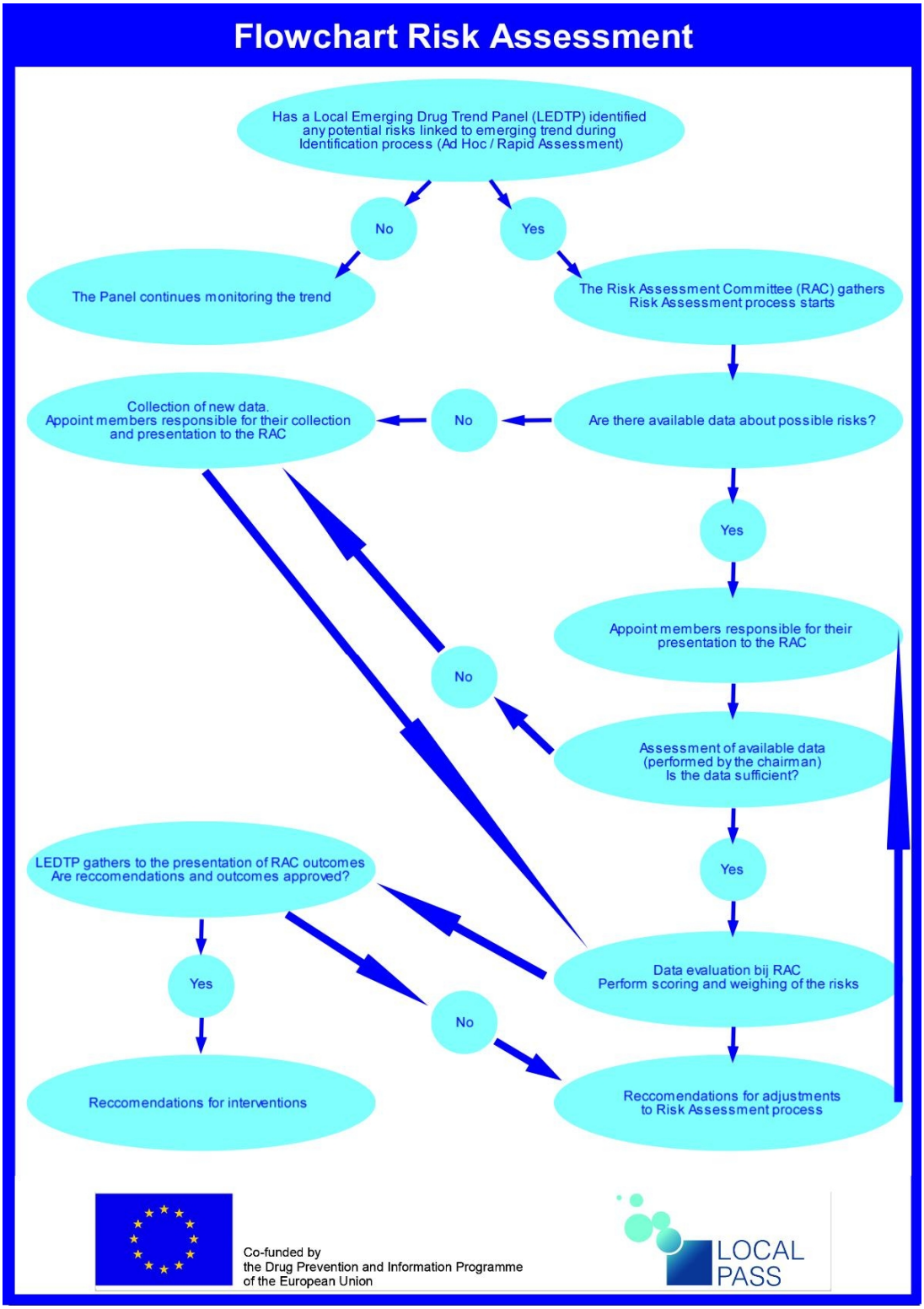
II. LOCAL RISK ASSESSMENT SCHEME

Figure 1: A schematic representation of Risk Assessment of new trends in substance use on the local level.



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III. THE RISK ASSESSMENT PROCEDURE

Local Rapid Assessment and Risk Assessment bodies

To identify new trends in new psychoactive substance use and assess their risks early on, we recommend a Local Emerging Drug Trend panel (referred to as "LEDTP" or "panel") be set up. Please see the Local PASS toolkit Guideline for its composition and installation. Its members should represent a spectrum of backgrounds and professional practice. Professionals who work with all groups of drug users and populations at risk are advised to be involved, as well as representatives of research, local policy coordination and other stakeholders – including drug users themselves. The panel is recommended to meet on a regular basis. Meetings in person can be partially replaced by an online communication platform.

The Risk Assessment process is triggered by LEDTP's decision that recommends the assessment of risk of a newly identified trend. National level bodies such as a national Early Warning System or a National focal point can also suggest to perform a Risk Assessment.

Since the Risk Assessment process is time consuming, we advise to only have potentially risky trends undergo an RA process. This process demands expertise, practice and time effort from LEDTP panel members. Therefore, we recommend performing Risk Assessment at three levels:

1. AD HOC/ Rapid Assessment as a part of the IDENTIFICATION process by relevant members of the LEDTP panel

Short description: When the panel meets for evaluation of data from the Map of Data Sources (see Identification Guideline) and an emerging trend in the locality is identified, review of any information on potential risks will be performed. The panel briefly assesses whether there are potential risks. If there are, the panel recommends a Risk Assessment process of this trend (the IRI model proceeds to its second phase, see Local PASS Toolkit Guideline). If no potential risks are identified, the trend is followed for further developments. This AD HOC assessment is performed by previously agreed members of LEDTP.

Benefits: Only identified trends with potential risks "enter" the Risk Assessment process of the IRI model. Other hypes, rumours or trends without risks are further monitored within the Identification process. This brief assessment procedure is an important part of the Identification process that constitutes a bridging procedure between the Identification and Risk Assessment processes.

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2. Risk Assessment Committee and its chair appointed by the LEDTP panel proceed with the Risk Assessment based on the recommendations of the brief assessment from the Identification process

Short description: A Rapid Assessment Committee ("RAC" or "committee") of 2 – 5 members is composed and elected from members of the LEDTP. The members of the Rapid Assessment Committee should have good insight into and access to the most relevant datasets and / or risk groups involved in the new trend, and have basic research skills. More detailed procedures will apply to their work, and we therefore advise that they are trained in Risk Assessment procedures.

Benefits: There is no need for the whole LEDTP to be involved in the RA meetings, which saves time. In addition, data about risks are collected under supervision of experienced panel members.

3. Full LEDTP panel meets to approve / adjust the recommendations of the RAC committee and suggest interventions

Benefits: All members of LEDTP are acquainted with the results of the Risk Assessment process. When all members are present they help make decisions on the severity of the risks and help with preparing recommendations for the Intervention process. While some trends or hypes do not proceed to the Risk Assessment process, most likely all trends that undergo Risk Assessment will proceed to Intervention phase (the third phase in the IRI model, see the Local PASS Toolkit Guideline).

The functioning of the Risk Assessment process needs to be ensured by key players within the local drug policy. Involvement of all mentioned parties in this process is advised to be promoted and, in an ideal case, financed by the local public services. These services are advised to promote the Risk Assessment process as support for evidence-based planning of appropriate services in their drug policy system. The enthusiasts who will be supporting this process are extremely valuable.

Rapid Assessment and Risk Assessment procedures – what is being assessed and how?

The types of risks of new drug trends that need to be assessed on the local level are similar to those assessed nationally and internationally. In the course of the Local PASS project the types of risks assessed on the European level by the European Monitoring Centre for Drugs and Drug

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Addiction (EMCDDA) are discussed with local stakeholders, and adjusted to the local level. The typology of risks is outlined in Table 1.

Table 1: Types of risks assessed on the local level.

TYPES OF DATA ON INDIVIDUAL HEALTH RISKS
- effects of the substance
- content of substances
- toxicity and acute adverse events (health-related incidents)
- long-term adverse events (brain damage, addiction etc.)
TYPES OF DATA ON PUBLIC HEALTH RISKS
- description of the user groups
o possible engagement of vulnerable user groups
- risky context of use and its setting
- criminal aspects of the trend
- risks for the municipality - public safety and nuisance - availability of the substance
TYPES OF DATA ON INTERVENTION-RELATED FACTORS
- risk perception among the users
- reasons for the users to engage in the "new trend"
- context of national drug policy and consequences of intervention
- demand for intervention

AD HOC/Rapid Assessment procedure

When a new trend has been identified, the Local Emerging Drug Trend Panel can perform an AD HOC / Rapid Assessment. This requires that (i) all relevant stakeholders are present or that information is supplied via an Online Communication Platform (see the Local PASS Toolkit Guideline), and that (ii) the risks to the local community have been demonstrated by the known data.

The overall aim of the Rapid Assessment is to decide whether there is any indication of risks to the local community from the newly emerged trend in substance use. If there is, a more elaborate Risk Assessment will be performed. A majority voting rule can be used to decide whether this is needed.

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If relevant stakeholders are not present at the meeting, we recommend the panel chair to gather their position statements, supported by any relevant data, as soon as possible. The importance of Rapid Assessment in this case is to prevent an elaborate and time-consuming Risk Assessment when not needed (i. e. when it is obvious that no risks from the new trend exist, such as in the case of decline in use of certain substances or adoption of safer drug consumption practices).

Recommendations

- The Rapid Assessment can be performed AD HOC.
- The outcome of the Rapid Assessment is a decision whether to perform a more extensive Risk Assessment.
- The Rapid Assessment indicates whether there are potential risks of the new trend in substance use to the local community

Risk Assessment on the local level

In case relevant stakeholders decide with a majority rule that there are potential risks related to the new trend on the local level, the LEDTP will set up a Risk Assessment Committee ("RAC" or "committee") from its members, and appoint the person in charge of the Risk Assessment. The process of Risk Assessment is a time-consuming procedure and needs only be conducted when there has been an initial Rapid Assessment of risks.

The tasks of the Risk Assessment Committee are to:

- gather all data related to the risks of the new trends in substance use,
- assess the relevance of the data and evaluate the data to decide about the risks of the trend,
- present the outcome of the Risk Assessment to the full which LEDTP that will then approve / adjust its findings and suggest (an) appropriate intervention(s).

The local Risk Assessment procedure is strongly oriented towards providing guidelines for effective intervention. While on the national and international level the outcome of Risk Assessment usually leads to adoption of control measures (e.g. supply reduction), on the local level preventive and harm reduction interventions are more plausible (e.g. demand reduction). The intervention recommendations will be specific and relative to the field of each panel member. They may arise from data interpretations or can be proposed by each member based on his or her professional expertise.

For the purpose of Risk Assessment we recommend that at least one panel (and committee) member has access to the European Early Warning System (EWS) administered by the EMCDDA. In

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case a new substance is identified in the locality, information about its pharmacology (or pharmacology of similar compounds) and related risks might be available through the EWS.

Final assessment performed by full LEDT Panel

After the RA committee finalises the risk scoring and weighing process (see section IV), the full LEDT panel meets to approve or adjust the recommendations of the RA committee, and suggests appropriate interventions or adjustments to the Risk Assessment process.

IV. RISK ASSESSMENT TOOL

Data collection check list by the Risk Assessment Committee

The RAC will gather and agree on the collection of data concerning risks posed by a newly emerging trend. The data can be collected from (i) already existing sources of data or (ii) new sources, through several methods. For a detailed outline of possible data sources that can serve both identification and Risk Assessment purposes, see Appendix 1 or the Local PASS Identification Guideline. The steps necessary for collecting data for the Risk Assessment procedure are the following:

- Identify all existing data sources related to individual health risks, public health risks and to intervention-related assessment.
- The chair of the Risk Assessment Committee is recommended to approach the data custodians, or to appoint committee members in charge of approaching them.
- Identify the gaps in the current data and suggest feasible methods of gathering the necessary information.
- Coordinate data collection, if needed.
- Compile a database of all existing data sources and make it accessible to all members of the Risk Assessment Committee

Checklist for all relevant data for Risk Assessment on the local level

The amount of data that needs to be collected and the specific sources need to be defined by the RA committee beforehand. The data should be collected and/or aggregated with respect to the risk categories defined in Table 1. The data checklist is guided by the following principles:

- use of existing data gathered through the Local Emerging Drug Trends Panel,
- collection of new data, if no indication of risks exist or if there are no data specific to the risk group,
- if possible, the data should be specific to the locality or region,

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- Early Warning System data or review of scientific / grey literature might be particularly helpful when dealing with new psychoactive substances. When literature is insufficient research on online drug fora is strongly recommended.
- data should be easily accessible and/or expandable given the composition of the Local Emerging Drug Trends Panel and its data map.

We advise that the data is collected continuously, and stored into databases according to specific substances (i.e. a register of case reports from emergency rooms; a database of case reports from drug users, etc.). The better available the data, the quicker their assessment can be performed. Once the data have been gathered the Risk Evaluation Checklist and Scoresheet can be filled out (see Figure 2). Specifically the fields (i) Checklist data available Y/N, (ii) Data sources (summary of main findings), and (iii) Relevance and sufficiency of data have priority. If the committee members identify significant gaps in the data a reasonable time frame needs to be agreed upon for filling them in. A first risk scoring can only be performed if the RA committee considers the data both sufficient and relevant.

Recommendations

- The relevance of the data for the local community needs to be carefully assessed.
- All data should be presented to all members of the RA committee so they have time to analyse them.
- The data can be presented by the experts in a raw form or short summary, and a basic interpretation can be prepared by relevant authorities in the RAC.
- Interpretations of the data need to be very basic, so they do not influence independent opinions of the panel members (who need to independently assess the risk of the identified trend, see next section).
- The data should be always triangulated (e.g. verified by more than one source) and summaries need to be reviewed by another relevant panel member who will confirm their interpretation.

Data evaluation score sheet for Risk Assessment Committee

After all relevant data have been collected and made accessible to all members of the Risk Assessment Committee, the committee shall perform an overall evaluation of the relevance of the data and quality, and an assessment of the identified risks – i.e. proceed to scoring of the risks. This, in the ideal case, will be performed on a face-to-face meeting where all RAC members are present. If

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this is not feasible, the RAC chair asks all the committee members to fill in the score sheets separately, and then aggregates the outcomes.

A pre-filled Risk evaluation Checklist (see Figure 2) of relevant criteria is provided to the committee members at the start of the process. Each member will need to separately evaluate each criterion. On each level of risks risk scores are then assigned, taking into account the availability and quality of the data on a particular indicator. Where data is not available, or the quality of the data is poor, the particular risks cannot be assessed reliably. Below we provide suggestions on how risk scores can be assigned:

- Each category of risks will be assigned an ordinal risk score (preferably on a 5-point scale).
- For each category of risks a weight can be assigned on a scale from 1 to 3 that will reflect the overall importance of a particular risk category in the overall assessment. For instance, while the criminal risks of the trend might not be a concern to a particular community and would be assessed as 1, involvement of vulnerable user groups could be of a high concern and be assessed as 3.
- The total sum of the risk score will not only reflect the risk scores, but also the weights assigned to the risk.
- The total risk score should always be broader than YES / NO and should always incorporate suggestions for interventions – see the next chapter for the involvement of the LEDTP.

The committee can further reassess its conclusions over the risks during the meeting, if any discussions arise. Finally, a conclusive Risk Evaluation Checklist and Score sheet is passed on from the RA committee to the full LEDT panel.

Final assessment and recommendations for intervention by the Local Emerging Drug Trends Panel

The chair of the RA committee will prepare a final summary of findings regarding the risks of the new drug trends for the LEDT panel in the form of the Risk Evaluation Checklist and Score sheet (see Figure 2), and a brief summary of findings. In case the LEDT panel considers the findings to be inconclusive, it can ask the RA committee for adjustments. It is beneficial if the panel members express their concerns prior to the panel meeting, so that the adjustments can be made by that time.

When the panel meets, apart from approving the risk scores as presented by the RAC, recommendations for interventions can be made by the panel members. The last section of the Risk Evaluation Checklist and Score sheet (Recommendation for intervention) can be filled in.

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Please note that follow-up of the trend is always desirable, because trends evolve over time and their harms are subject to change. Also, when a new trend with alarmingly high risks is assessed, the local level should initiate a Risk Assessment process on a general (national/international) level.

The outcome of the Risk Assessment procedure will lead to implementation or development of interventions, if risks have been identified. Any outcome of the Risk Assessment procedure can be communicated to the local, as well as national authorities, with reference to the Local PASS Risk Assessment Guideline.

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Figure 2: The Local PASS Risk Assessment tool: Risk Evaluation Checklist and Score sheet

1.	TYPES OF DATA ON INDIVIDUAL HEALTH RISKS	TO BE FILLED IN BY THE *RISK ASSESSMENT COMMITTEE*				TO BE FILLED IN BY THE *LOCAL EMERGING DRUG TRENDS PANEL*
		CHECK LIST – DATA AVAILABLE Y / N	Data sources (summary of main findings)	Relevance and sufficiency of data	Risk score (1 – 5)	Recommendation for intervention
1.a.	effects of the substance					
1.b.	identification of substance content					
1.c.	toxicity and acute adverse events (health – related incidents)					
1.d.	long-term adverse events (brain damage, addiction etc.)					
2.	**TYPES OF DATA ON PUBLIC HEALTH RISKS**	**CHECK LIST – DATA AVAILABLE**	**Data sources (summary of main findings)**	**Relevance and sufficiency of data**	**Risk score (1-5)**	**Recommendation for intervention**

		Y / N				
2.a.	description of the user groups					
2.b.	indications of spreading the trend into different user groups / (possible) engagement of vulnerable user groups					
2.c.	context of use and its setting					
2.d.	availability of the substance					
2.e.	criminal aspects of the trend					
2.f.	public safety and nuisance					
2.g.	risks for the municipality					
3.	**TYPES OF DATA ON**	**CHECK LIST –**	**Data sources**	**Relevance and**	**Risk score**	**Recommendation for intervention**

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	INTERVENTION-RELATED FACTORS	DATA AVAILABLE Y / N	(summary of main findings)	sufficiency of data	(1-5)	
3.a.	users' risk perception					
3.b.	reasons for the users to engage in the "new trend"					
3.c.	context of national drug policy and consequences of intervention					
3.d.	demand for intervention					

SUMMARY

To assess the risks of new trends, first an AD HOC / Rapid Assessment among the relevant stakeholders in the Local Emerging Drug Trends Panel will be performed. If there is an indication of risks to the local community, a Risk Assessment Committee shall be set up to perform a full data collection and to evaluate the risks. The risk categories to consider are individual health risks, public health risks and risks related to interventions. After the RAC makes a comprehensive assessment, a meeting of the full LEDTP panel will be held where the final confirmation will be taken on whether the risks of the trend are low, moderate or high, together with a recommendation for intervention(s).

If any evidence is inconclusive, the panel members can communicate this back to the RA committee prior to the full panel meeting, and the RAC will make an effort to fill in gaps in the data. Outcomes of the Local PASS Risk Assessment should be communicated to the local and national authorities. In this way, further spread of the trends can be prevented, and attention to the problem and the possible needs for funding of interventions are based on evidence and are well-documented.

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APPENDIX 1

The Local PASS Identification tool: Map of Data Sources for effective early identification of new trends in substance use on the local level (see also Identification Guideline)

	Type of data	Description	Source of data / responsible person	TO BE FILLED IN BY EACH PANEL MEMBER ON THE 1st PANEL MEETING			TO BE FILLED IN BY THE PANEL CHAIR AT EACH MEETING		
				Available in my institution *(Y / N)*	**Periodicity of the data** *(1 – casual, 2 – regular upon client intake, 3 – regular upon (what) periodicity, 4 – AD HOC)*	**Format of the data to be shared with the panel** *(1 – oral reporting, 2 – aggregate report, 3 – raw data for panel use)*	**Data reported (Y / N),** *if yes, list and number the sources*	**New trend in substance use reported (Y / N)** *If yes, summarize the trend, and indicate the source by number*	**Quality of the data** (1 – rumour, 2 – weak indication of a trend, 3 – strong indication of a trend)
INFORMAL COMMUNICATION	Informal communica-tion within the population involved in the trend and their family members	*Drug user services (low threshold, street work programs, nightlife programs, treatment centres, online counselling services)*	Members of the local identification panel employed in these organisations						
		Emergency room doctors, paramedical personnel, psychiatric facilities	Members of the local identification panel employed in these organisations						

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QUALITATIVE DATA	Observations , case studies	*Drug user services (low threshold, street work programs, nightlife programs, treatment centres, online counselling services)*	Members of the local identification panel employed in these organisations						
		Emergency room doctors, paramedical personnel	Member of the local identification panel employed in these organisations						
		Psychiatrists from the acute psychiatric facility, other personal information, detoxification units where available	Member of the local identification panel employed in these organisations						
		Drug user web-based discussion forums	Researcher, someone who performs it as a part of his job						
		Psychonaut reports	Researcher, someone who performs it as a part of his job						
QUALITATIVE DATA	Semi structured	*Interviews with drug users (e.g. field research projects), or key*	Researchers, members of the local identification						

	interviews	*informants (members of the local identification panel- information can be gathered at local identification panel meeting)*	panel who work directly with drug users						
	Focus groups	*Focus groups with drug users (e.g. field research projects) or key informants (performed via local identification panel meeting*	Researchers, members of the local identification panel who work directly with drug users						
	Media	*Local or regional newspaper, magazines, internet magazines*	Appointed members of the local identification panel ; the relevance of the data needs to be assessed carefully						
QUANTIATIVE	Epidemiological data, statistics	*National focal point, local or national health units*	Members of the local identification panel from local health / drug coordination unit						
	Surveys	*Surveys among the drug using population*	Researcher, someone who performs it as a						

		(nightlife settings, problematic drug users, youths on the street, web based surveys, school population)	part of his job						
	Police statistics	*Local police units, regional police units, drug enforcement agency data (the data need to be local specific)*	Members of the local identification panel from local police						
	Drug seizures	*National police statistics, drug enforcement agency, customs authority statistics (the data need to be local specific)*	Members of the local identification panel from local police						
	Other statistics (Drug checking statistics)	*Local or national drug checking service, nightlife programs, short-time drug checking projects (if available in the locality)*	Appointed members of the local identification panel						

	Other statistics (Toxicology/forensics unit statistics)	*Toxicology department statistics, forensic department statistics, national focal point, local health units*	Members of the local identification panel who work in these organisations						
OTHER SCIENTIFIC METHODS	Wastewater analysis	*Local university, research centre, hygienic / water stations*	Appointed members of the local identification panel, if such data is available						
	Drug sample analysis	*Local or national drug checking service, nightlife programs, short-time drug checking projects (if available in the locality)*	Appointed members of the local identification panel, if such data is available						
	Atmospheric pollution research	*Specific research methods aimed at identification of substances in different geographical areas*	Appointed members of the local identification panel, if such data is available						
	Availability of NPS in	*Online web-forums, discussion forums,*	Researcher, police or someone else who performs it						

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	online shops	*websites of smart shops,*	as a part of his job						
	Illicit drug reporting systems	*Local early warning system; local mechanisms of data gathering and assessment*	Should be accessible by all local identification panel members, incorporated in the local identification, risk assessment and intervention process						
	Multi-component laboratory	*Laboratory methods aimed at identification of substances by various methods*	Researcher or police						
	Poison control centre data	*Data of controlled substances in the local area*	Members of the local identification panel from local health / drug coordination unit						