Final PDU REVISION PROPOSAL

for discussion at the 2012 PDU annual expert meeting

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Introduction

This document is a summary of the proposed concepts and definitions in the revised area. The proposed changes are, for the most part, related to the theoretical component of the indicator. Data collection recommendations will remain mostly unchanged with two exceptions: the addition of intensive cannabis use data collection based on general population surveys data, and making provision for interested countries to report on other - including new - drugs.

"Prevalence of problem drug use" was established as one of the five key epidemiological indicators to monitor drug situation (EU Council CORDROGUE 67, 2001). Its purpose was from the beginning defined as: "to provide comparable, reliable estimates of the prevalence and patterns of more severe drug use" (EMCDDA Management Board, 2001). The importance of and difficulty finding a common definition of "problem drug use" was understood from the beginning. In 2004 methodological guidelines, a pragmatic operational definition, applicable across diverse data sources, was published: "Problem drug use is injecting drug use or regular and/or long-term use of opiates[1], cocaine and/or amphetamines."

The work under the indicator area relied predominantly on indirect statistical extrapolations from existing data sources. These resulted often in estimates of populations of heavy, mostly marginalised, opioids users.

The main motives for the revision of the key indicator were: a changing drug situation and the increasing importance of knowing the prevalence of new groups of users (like heavy cannabis use and heavy stimulants use without the presence of opioids use, new drugs, etc), changes in the nature and availability of data sources, a missing conceptual framework and its link with operationalised definitions and, finally, confusions around the area name (including unwanted labelling). Additional issues that needed to be addressed are the limited capacity of the content of the current area to monitor adequately trends over time and characteristics of the drug users in question.

The process of revision involved expert meetings and discussions, first proposal in 2011[2], an online survey in 2012, several bilateral discussions with experts and scientists and a finalised proposal at the end of 2012. After consensus has been reached, all changes should be implemented in updated indicator guidelines and other indicator-defining documents.

[1] "opiates" were later changed to "opioids"

[2] Detailed documents on these steps in the process are available from the EMCDDA: 1. Principles of PDU revision, February 2012 and 2. Problem Drug Use key indicator reconceptualisation / revision 2012: results of an online survey collecting comments on the process from all EMCDDA member states and some independent scientists, May 2012

The PDU/revised

The revised indicator focuses on "high-risk drug use". The term "high risk drug use" means **"drug use that is causing actual harms (negative consequences) to the person (including dependence, but also other health, psychological or social problems) or is placing the person at a high probability/risk of suffering such harms"**[3].

The principal task of the indicator is to estimate annual prevalence of high risk drug use, or the sizes of populations with high risk drug use. These estimates are calculated and reported to the EMCDDA in a standardised way (according to existing guidelines).
At the same time, more emphasis will be put on increasing the ability of the indicator area to report on trends in high risk drug use. This is, however, still a developmental area (see below).
Other important tasks are to give some insight into the characteristics of these populations by utilising information through collaboration with the TDI key indicator, which collects standardised data on the characteristics of what can be thought of as a broad sample of high risk drug users and also data from diverse studies using non-treatment data sources (reporting the results through annual national reports). Further, incidence of this behaviour, estimated in scientific studies, is a useful element to complement the understanding of the situation.

Substances included in the monitoring are the most harmful and sufficiently prevalent illegal/illicit substances, i.e. those which are causing most harm (predominantly to an individual user, but also at the user population level depending on the intensity of harm and prevalence of use). Potentially harmful, but rarely used, substances are excluded from the monitoring (please refer to the Early Warning System for these).

The studies indirectly estimating the sizes of populations with high risk drug use, which are at the core of the indicator, should be planned and conducted with having in mind their utility in informing policy about the need of drug treatment. It is important to explicitly formulate this, because it, to some extent, determines the data sources and case definitions that need to be used in prevalence studies.

> Drug treatment definition spelled out in the TDI protocol (and also EMCDDA Treatment CUP) applies: "Drug treatment is defined as an activity (activities) that directly targets people who have problems with their drug use and aims at achieving defined aims with regard to the alleviation and/or elimination of these problems, provided by experienced or accredited professionals, in the framework of recognised medical, psychological or social assistance practice."

The conceptual framework translates into a definition, further operationalised by drug, which suggests how to measure "high risk drug use": **"High risk drug use is the illicit use of psychoactive substances by high risk pattern (e.g. intensively, in binges) and/or by high risk routes of administration in the last 12 months."**
Note: "Intensively" is further defined by drug. For the definition of "binge" please see below under cocaine and amphetamines sections.

[3] The text in quotation marks can be considered a theoretical or conceptual definition of the area.

Three elements of the final revision proposal are elaborated in the following sections:

a) Estimates of prevalence of high-risk drug use
b) Monitoring of characteristics of high risk drug users and trends
c) Opioid substitution treatment (OST) clients in the revised indicator

A) Estimates of prevalence of high-risk drug use

The following estimates are to be derived at national (and if possible sub-national) level and reported to the EMCDDA:

1. High risk opioids use (comparable to previous "problem opioid use")

Case definition at the level of the data source, in the order of preference:

1. Use of opioids including opioid medicines daily or almost daily[4] in at least one month of the past year, not according to medical prescription.

OR

2. a medical diagnosis according to current DSM or ICD criteria, e.g. "harmful use or abuse or dependence on opioids or opioid use disorder" (diagnosed in the past 12 months)

OR 3. any other best proxy of the above which can be collected at the level of the data source for the last year e.g. if drug treatment data is used, the best available proxy can be "any demand for treatment due to opioids as a primary or secondary drug." Or if criminal justice data is used, an example proxy definition can be "registered by police due to possession of opioids, under laws not related to drug trafficking/dealing".

Note: opioids users who satisfy the case definition but who are stabilised on opioid substitution treatment are, if possible, reported separately. See section on handling of OST cases.

Methods and data sources: indirect estimates with their respective data sources (see indirect estimation guidelines).

2. Injecting drug use

Case definition: Injecting use of any psychoactive substance(s) not according to medical prescription in the last year.

Methods and data sources: indirect estimates with their respective data sources (see indirect estimation guidelines)

OPTIONAL: breakdown by injected substances

3. High risk cocaine use (compared to previous "problem cocaine use")

IF RELEVANT FOR COUNTRY'S DRUG SITUATION AND FEASIBLE:

Case definition at the level of the data source, in the order of preference:

1. If frequency of use data is available, one or more of these three conditions should be fulfilled:

[4] The EMCDDA definition of "daily or almost daily" applies, i.e. daily or almost daily use is use on at least 20 days in a month.

a) Use of cocaine daily or almost daily[4] in at least one month of the past year.

b) Use of cocaine weekly or more frequently in the past year for at least six months (alternatively can be measured as 24 days or more in the past year).

c) Use of cocaine in binges in the past year (defined as use of cocaine continuously for 48 hours or more).

OR

2. a medical diagnosis according to current DSM or ICD criteria: "harmful use or abuse or dependence on cocaine or stimulant use disorder"

OR

3. any other best proxy of the above which can be collected at the level of the data source e.g. if drug treatment data is used, the best available proxy can be "any demand for treatment due to cocaine as a primary or secondary drug".

Methods and data sources: 1. indirect estimation methods with their respective data sources (see indirect estimation guidelines), new data sources to be sought and tested (like emergency room visits, probation data, etc.), 2. alternative methods for more socially integrated part of this population – developmental work in progress with the general population surveys experts, other possibilities to be explored (e.g. waste-water analysis combined with modelling, incorporating information from targeted surveys)

4. High risk amphetamines use (amphetamine and methamphetamine: compared to previous "problem amphetamines use")

IF RELEVANT FOR COUNTRY'S DRUG SITUATION AND FEASIBLE:

Case definition at the level of the data source, in the order of preference:

1. If frequency of use data is available, one or more of these three conditions should be fulfilled:

a) Use of amphetamines daily or almost daily[4] in at least one month of the past year.

b) Use of amphetamines weekly or more frequently in the past year for at least six months (alternatively can be measured as 24 days or more in the past year).

c) Use of amphetamines in binges in the past year (defined as use of amphetamines continuously for 48 hours or more).

OR

2. a medical diagnosis according to current DSM or ICD criteria: "harmful use or abuse or dependence on amphetamines/other stimulants or stimulants use disorder"

OR

3. any other best proxy of the above which can be collected at the level of the data source For example, if drug treatment data is used, the best available proxy can be "any demand for treatment due to amphetamines as a primary or secondary drug"

Methods and data sources: 1. indirect estimation methods with their respective data sources (see indirect estimation guidelines), or possibly new data sources, 2. alternative methods to be explored (e.g. waste-water analysis combined with modelling, general population surveys, possibly combined with targeted surveys).

5. Estimates of overlaps between the above-mentioned groups, accounting for multiple drug use and poly-drug use

The above-mentioned figures are to include all users of the drug in question who have the specified pattern of use, regardless of whether they use other drugs or not. Thus, there will exist overlaps between the four estimates.
The overlaps may be derived from existing surveys, in case of the impossibility to include them in the prevalence estimation study per se.

6. Total of the above-mentioned categories (after accounting for overlaps within the model)
OPTIONAL

7. High risk use of cannabis
SYNTHETIC CANNABINOIDS CAN BE INCLUDED IF THIS IS POSSIBLE AND RELEVANT FOR COUNTRY'S DRUG SITUATION
Case definition at the level of data source:
1. use of cannabis daily or almost daily in at least one month of the preceding year; in case of general population surveys this will be approximated by use of 20+ days in the month preceding interview,
OR
2. medical diagnosis according to current DSM or ICD criteria, e.g. cannabis abuse/harmful use or dependence or cannabis use disorder in the past year. For the purpose of monitoring this phenomenon at the level of general population surveys, this will be approximated by short psychometric scales (see the respective upcoming guidelines).

Methods and data sources: At present, this means two separate estimates based on general population surveys. One is the estimate of daily or almost daily users, which can be obtained by incorporating the frequency of use in the past month question. The second figure – an estimate of the prevalence of "cannabis use disorders" applies only to countries with sufficient cannabis use prevalence and/or sufficient sample size in the general population survey (guidelines in preparation). It is obtained by means of incorporating short cannabis scales in the general population surveys.

8. High risk use of other substances
OPTIONAL AND ACCORDING TO COUNTRY SITUATION
Other substances (according to national or regional need for the estimates): cathinones, GHB, benzodiazepines, volatile substances, other.

B) Monitoring of characteristics of high risk drug users and trends

Characteristics of high risk drug users

Besides knowing the prevalence of the phenomenon of high risk drug use, having an insight into the characteristics of users (for example, their age distribution, gender, drugs used, patterns of use, mental/physical health, social and legal problems) will be valuable. This is not only important in order to understand the drug situation but, even more so, in order to plan (an improvement of) public health interventions.

This component will utilise (i) data collected within the framework of TDI (Treatment Demand Indicator) as this represents best available data which can be considered as a broad sample

of high risk drug users as well as (ii) data/information collected by existing studies of data sources other than drug treatment (for example, seroprevalence studies, surveys at low threshold facilities, street population studies; see below).

Incidence of high risk drug use

Studies of incidence of drug use mainly inform about the current state within any possible epidemic curve from a long-term perspective and thus are very important element in the interpretation of long-term trends and service coverage. Possibilities for prediction are limited but exist.

Options for better understanding of current, possibly new, trends

The EMCDDA is preparing an inventory of bigger and sometimes national studies of drug using populations sampled from non-treatment data sources, more or less regularly conducted in most countries. These do not only provide insight into the characteristics of HRDUs, as mentioned above, but also into new trends in these groups.
Moreover, side by side with TDI data, the characteristics of individuals attending these two different settings can be compared, taking into account the complexity of the dynamic process of natural history of drug use including treatment entry, times in and out of treatment and active and inactive drug use state and so on.

Standard data collection in ST or SQ is not foreseen at the moment, but National reporting guidelines should be enhanced to improve the collection of this existing data. The ST7 Fonte template is expected to include space for references to these studies (primarily those in relation to data sources used in the regular prevalence estimation).

Other approaches should be tested, for example, building the information on change directly into all collection and estimation procedures (i.e. collecting data from drug users on their drug use not only in the last year but also in the year before). Wastewater analysis can serve as a basis for trends in community drug use, but research work and especially triangulation with other data is necessary to have a better idea how to interpret these.

C) Opioid substitution treatment (OST) clients in the revised indicator

The PDU indicator aimed to include all regular and/or long-term opioid users, including those on OST.

The issue of OST clients in high-risk drug use prevalence estimates has a “philosophical” and practical/data dimension. Regarding the first one, some argued that it is not correct from the perspective of motivation of the client and their rights, to call them “problem drug users” if they are stabilised, (almost) abstinent from illicit substances and perhaps also socially integrated. However, on the other hand, treatment coverage calculations – which include substitution treatment as an important element – need to have a denominator including OST cases.

Practical/data dimension becomes problematic only if the registry of OST clients – as opposed to solely new entries to OST – is used to calculate HRDU prevalence (e.g. in a capture-recapture study). This is because of (more serious) violation of homogeneity of capture assumption as long-term stable clients might have close to zero probability of appearing in other data sources, for example police data. Merging them with non-stable clients will thus result in a non-homogeneous population.
On the other hand, non-stable and/or new OST clients should naturally appear in HRDU estimates, if non-OST data sources are used or if entry to OST treatment instead of the full OST registry is used.

A solution was sought to overcome these problems (violation of homogeneity assumption on the one hand and need for treatment coverage calculations on the other hand).

It was thought that, as a first step, it would be useful to understand better the present situation. This should be achieved by adding some questions to ST7/Fonte, along these lines:
- Whether OST data set is used in estimation
- whether OST clients are or are not de facto included in the resulting opioids estimate
- or a part of them is included
- if a part of them, what is the definition of those included/excluded (this can be on the basis of case definition if OST data set is used or implied by method and data sources used and described after calculation of the estimates)
- what is the size of OST population in the country and which part of it is included (overlap with the estimate)

As HRDU by definition doesn’t include individuals who are on opioid medication used according to doctor’s prescription and do not use other drugs in a high risk way, in the future, data collection and reporting should be streamlined and improved in line with this. This means in practice that:

1. in case OST registry is used in estimation exercise (and not only entries to OST treatment in that particular year), a case definition is needed. This has to be developed in the near future.
2. in order to calculate OST coverage correctly and void of the above-mentioned methodological problems (violation of the homogeneity assumption), three elements (counts) will be needed: HRDUs not in OST treatment, HRDUs in OST treatment and stabilized OST clients. Work together with Health and Social Responses monitoring team is foreseen to agree how best to collect these element (e.g. from national studies or regular national OST statistics, in ST-7 or in ST-24, etc.).

3. some countries report that in their programmes (nearly) all OST clients are still HRDUs or that data collection following a specific case definition is currently not possible while the use of OST registry in estimation is inevitable. There will remain space for them to report in the best achievable way for them. Information on the used procedures/case definitions will be collected in ST-7.