The OPTIMUS Guidance on Opioid Agonist Maintenance Treatment (OMT) outcomes monitoring. Part A (guidance)

OPTIMUS outcomes monitoring guidance Part A - guidance

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1. About

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To use the OPTIMUS outcomes monitoring guidance please contact the authors.

This version of the guidance was adapted from Version 2 of the questionnaire (June 2025).

About the OPTIMUS project

The OPTIMUS project, coordinated by the EUDA, aims to establish international consensus on patient-reported outcomes for opioid agonist maintenance treatment (OMT).

Through a two-round Delphi study involving 757 participants from 26 countries, a six-domain outcomes questionnaire was developed, covering treatment, physical and mental health, social functioning, substance use, and quality of life.

The tool, endorsed by both professionals and service users, has been translated into 21 languages and refined based on extensive feedback. Feasibility testing, currently ongoing, evaluates acceptability and implementation in OMT services. OPTIMUS promotes harmonised, user-centred measurement of public health relevant OMT outcomes in order to help save and improve service users' lives.

[1] Although the guidance is meant to assist monitoring of OMT outcomes, the EUDA has at present no plans to set up central monitoring at European level. The guidance rather aims at supporting local or regional /national level OMT outcome monitoring to evaluate and improve care and treatment.

2. Summary and Introduction

An international group of experts in opioid treatment, including both professionals and service users, (Annex 1), developed the present consensus guidance for evaluating the treatment outcomes of people in opioid agonist maintenance treatment (OMT). The guidance includes an 'outcomes questionnaire' - Annex 2), intended for use in OMT practice. The central aim is to improve OMT care and treatment, by making them more focused on key health and social outcomes, and improving the comparability of OMT outcome measurements over time, both in a single service user and at group level, and across countries.[2]

There is a pressing need for high-quality and health-centred international consensus OMT outcomes monitoring guidance. Both the comparability of outcome measures across studies, and the inclusion of key health outcomes (e.g. overdose, HIV/HCV, risk behaviours), were found to be lacking, in a systematic review of opioid treatment outcome studies (Wiessing et al. 2017). Moreover, a lack of systematic drug treatment outcomes monitoring, as well as a lack of comparability among the countries where monitoring existed, were confirmed in a series of EUDA workshops with treatment experts from across the European region (Annex 3).

Long-term continuous opioid treatment, rather than short term 'recovery'-oriented treatment, is key to prevent overdoses, mortality and other health problems (e.g. HIV) in people who use opioids (PWUO). OMT with methadone or buprenorphine reduces mortality by a factor of three to five (Santo et al., 2021; Sordo et al. 2017), prevents key causes of death, including overdose, suicide, HIV, hepatitis B and C virus infections, and injuries (Degenhardt et al. 2019, Metzger et al. 1993), improves health-related quality of life and levels of addiction and illicit drug use (Torrens et al. 1999; Feelemeyer et al. 2014; Farré et al. 2002, Mattick et al. 2002) and decreases drug-related offences and incarceration rates (Carrieri et al. 2017, Sun et al. 2015, Marsch 1998).

The guidance was developed by experts from 30 countries[3], and was translated and tested in 21 languages, during a consensus ('Delphi') study (Annex 4; Wiessing et al, 2023; Wiessing et al., in press). For this, the experts recruited a Delphi panel of 757 further experts in their countries (about 16-20 per country), who were consulted in two survey rounds. The panel included both OMT professionals and service users (46% were service users, 40% were female - for panel composition protocol see Annex 4). Panel members provided open comments on the draft outcomes and expressed their level of agreement on a 1-6 Likert scale for each outcome and for the total list. Levels of agreement were high already in round 1, with an average of 5 out of 6 for almost all outcomes and only slight deviations on some, and increased to a mean of 5.2 in the second round (Wiessing et al., in press).

The outcomes questionnaire consists of a list of 26 core questions, measuring 13 outcomes in six domains (see Box 1 and Annex 2). It also has an additional list of 'optional questions' that can be added to the core questions if the service provider deems this necessary, for example if a specific problem area is detected through the core questions. There are also specific questions and

[2] Although the guidance is meant to assist monitoring of OMT outcomes, the EUDA has at present no plans to set up central monitoring at European level. The guidance rather aims at supporting local or regional /national level OMT outcome monitoring to evaluate and improve care and treatment.

[3] Australia, Albania, Belgium, Bosnia and Herzegovina, Canada, Cyprus, Czechia, Denmark, Finland, France, Georgia, Germany, Greece, Hungary, Ireland, Israel, Latvia, Lithuania, Netherlands, North Macedonia, Palestine, Poland, Portugal, Qatar, Serbia, Slovakia, Spain, Switzerland, UK, Ukraine

information to start and to end the OMT session (5 questions in the 'START' and 6 questions in the 'END' section), and a set of 12 baseline questions (in a 'BASE' section), which are only asked the first time. It is recommended to repeat the core questions (plus START and END questions) regularly, e.g. every 3 months, to follow changes in the service user outcomes over time and to allow for timely intervention if needed (later-on this can be changed to longer intervals, e.g. every 6 or 12 months, depending on the person) (see Box 2).

The six domains (with 26 core questions /13 outcomes) are: A. "Treatment" (5 core questions / 2 outcomes), B. "Physical health and risks" (11 core questions / 5 outcomes), C. "Mental health" (2 core questions / 1 outcome), D. "Social functioning" (4 core questions / 3 outcomes), E. "Substance use" (2 core questions / 1 outcome), F. "Quality of Life" (2 core questions / 1 outcome). Together they cover the three areas of the WHO definition of health[4] as well as a range of specific (e.g. overdose, HIV/HCV; substance use) and further issues associated with high-risk opioid use (see Box 1 and Annex 2).

The outcomes questionnaire is designed to be directly applicable in an interview with the service user. It is hoped that asking the core questions is feasible in most routine OMT service visits, whereas the optional questions provide a tool for the interviewer to go more in-depth on one or more specific areas if necessary and more time is available (see Figure 1). The outcomes questionnaire (core questions) can be applied directly at the start of treatment (e.g. this can be on the second day if the TDI[5] questionnaire has been taken on day 1). The optional questions are available for more in-depth evaluation of any specific area if the core questions suggest a need for it (this can be either done immediately or in a subsequent visit e.g. on day 3) after which further action, e.g. a need for referrals, can be evaluated.

The guidance is intended to be service user-centred, thus avoiding jargon (for example the group prefers to use the acronym OMT rather than OAT - see Annex 5) and focusing on the person's personal experiences with their treatment, health, quality of life etc. rather than focusing on service provider-reported or laboratory outcomes. For example, the group rejected the use of urine testing to detect illicit drug use and recommended only to use it for the initial diagnosis to initiate opioid treatment. Additional non-service user reported data may be also collected separately, provided ethical and data-protection requirements are met, to allow for evaluating system level outcome indicators such as retention and treatment participation across services or to enable data-linkage studies (e.g. mortality, population size /OMT coverage estimation, etc. - see section 'Data management and analysis').

A service user-centred approach should result in a lower threshold for people who use drugs to access treatment (and remain in treatment) which is one of the key factors for improving the health and wellbeing (including the survival) of people who use opioids. Therefore the group also recommends that there should be no moral judgement nor any 'punishment' for service users who continue using illicit drugs or do not show up for scheduled appointments etc. Key is to make the treatment as accessible as possible (also to increase population-level coverage) and to provide agonist opioid medication (e.g. methadone, buprenorphine) according to the person's needs, for as long as necessary and without interruptions (see section 'Ten key principles of effective OMT', that summarise the expert group's discussions)

[4] The preamble to WHO's constitution provides a definition of health: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"

[5] TDI (Treatment Demand Indicator) is an instrument developed to describe the population of people who use drugs entering substance use treatment. https://www.euda.europa.eu/publications/manuals/tdi-protocol-3.0

The OPTIMUS guidance intends to simultaneously provide improved OMT outcome indicators for individual service user follow-up and treatment as well as for national and regional (local) drug treatment monitoring.

3. Aims, objectives and focus population

Aims and objectives of the guidance

To improve OMT care and treatment, by implementing consensus guidance on OMT outcomes monitoring that is service user-reported and with a central focus on survival, health and quality of life.

The outcomes are intended:

1) for use in OMT practice (to evaluate a service user over time)
2) for improving the comparability and (public) health relevance of OMT outcomes
3) for future analyses (e.g. cohort study evaluating predictors of outcomes)

Treatment objectives[6]

1. Survival
2. Improve health and support treatment of physical and mental comorbidities
3. Risk reduction[7]
4. Reduction of harmful substance use
5. Social participation
6. Quality of life improvement

Definition of the focus population and intended readership

The focus population for this guidance is: All people who initiate an OMT or are on stable OMT.[8]

This guidance is intended to be read by those involved in providing OMT at any level. The readership falls into three broad groups: 1) policy makers and administrators who make decisions on the availability

[6] Adapted from 2017 German treatment objectives (Bundesärztekammer, 2017)
[7] Specific conditions that risk reduction is focused on may include: HIV or HCV infection, overdose, worsening substance use disorder, degradation of social connections etc.
[8] Relevant domains may be used on other focus populations such as users of stimulants or when an OMT service user intentionally (and/or temporarily) suspends medication while continuing treatment/care. However, using the guidance for other focus populations may require additional considerations. The decision who initiates OMT, or should initiate OMT, is for the clinician to take, based on evidence-based clinical recommendations and protocols e.g. national or WHO clinical guidelines (WHO 2009).

of medicines and the structure and funding of services in their countries or in subnational health administrative regions 2) managers and leaders responsible for the organization of specific health-care and social services, and for the care those services provide 3) health-care and social workers involved in providing OMT to service users within the health-care system. (adapted from WHO 2009)

3. Ten key principles of effective OMT

The wider context of this guidance can be summed up in ten key principles of effective OMT, which summarise and emerged from the expert group's discussions:[9]

Ten key principles of effective OMT

1. Effective OMT is easily accessible with no waiting lists nor waiting time after assessment, no requirement to stop using illicit drugs, no costs or very low costs for the person, generous opening times, no compulsory social /psychological interviews ('just take the medicine and leave again if you prefer')[10], no police interference, available in prisons and other restrictive settings etc.
2. People who use drugs are treated with respect, avoiding stigma, by all staff. Ideally there is a confidential counsellor (preferably not a service manager) where persons can make an (anonymous) complaint if needed. They are allowed to switch between services if they want to.
3. OMT is long-term and uninterrupted for the vast majority of PWUO. Detoxification (medicine-free 'recovery') is only to be attempted in a process of shared decision-making /consensual manner with the person and taking into account the clinical possibilities of sustained abstinence and with counselling /accompaniment if requested.[11]
4. Dosage is according to WHO recommendations and is assessed according to the person's needs and preferences. A lower than recommended dosage risks being not effective and causing relapse /treatment failure.
5. General health and social services are routinely available at the service (e.g. nurses and a psychologist plus a visiting clinician, referral to specialist health and social care).
6. Urine-analysis is preferably used only for first clinical assessment, and when it can help the person in their treatment or to help keep them safer, but not as a basis for treatment sanctions. Illicit drug use results in no negative consequences (punishment, expulsion) from the provider.[12]

[9] E.g. see the 2019 initial meeting report of the project, and Wiessing et al., (in press)

[10] Although WHO guidance prominently mentions psycho-social support of pharmacological opioid treatment (WHO 2009), recent evidence suggests the psycho-social support component is mostly not effective (thus potentially an important waste of time and resources) (Rice et al., 2020; Wild et al., 2021).

[11] For a clinician, there may be no confident way of knowing when there is a 'realistic' chance for success for detox. Instead, medically-managed withdrawal plans for patients may centre on the patient's informed choice - meaning, the clinician will partner with the patient to develop a medically managed withdrawal care plan only when the patient is fully informed of the risks and their other options and then make the choice to go forward with a medically managed withdrawal. The lack of evidence-based 'likely success' detox indicators underlines the risks and very high proportion of detox failure among PWUO.

[12] Drug testing has a weak evidence base as a therapeutic tool and has a history of being closely tied to coercion /punishment-based treatment approaches. When used for coercive or punishment purposes drug testing can do more harm than good and thus should be avoided. However, biological drug testing can inform the service user and the provider what substances the service user is being exposed to. This can be helpful during the initiation of treatment, so the service user and provider can understand what withdrawal syndromes the service user may be at risk for and how to manage them, and it can be useful during maintenance treatment phases, so that service users can be aware of what drugs are in the illicit drugs they are using.

7. The person is regularly assessed using a broad framework around health and quality of life (see the OMT outcomes questionnaire, Annex 2), not just on substance use and not with full abstinence from all opioids (including medication) as the primary goal. Reducing problematic substance use remains a key goal (non-abstinence based recovery).
8. There is special attention and resources are made available for special needs of women (which should have their own separate services or separate hours) and other vulnerable subgroups e.g., people with children or other care responsibilities, LGBTQI+ people, very young or old people, (undocumented) migrants or (ethnic) minorities, criminalised populations / people in contact with the criminal justice system in particular those coming in or out of detention, people with physical or cognitive disabilities, people in (rural) areas without suitable transport, people with irregular working times, people who cannot read, etc.
9. There are good connections to /routine collaboration /frequent meetings with other related services such as other harm reduction services, police, hospital /emergency care services etc, with a focus on uninterrupted care transitions.
10. Monitoring and analysis, e.g. in collaboration with or by academic institutions and people with lived experience, is essential to understand and improve the public health effectiveness of the local, regional and national OMT implementation efforts, including outcomes monitoring. Ideally, services should have the capacity and be funded to analyse and evaluate their own data and programs.

4. Six domains and 13 outcomes = 26 core questions (plus further optional ones)

Prioritisation of domains and outcomes

In a series of workshops with the expert group key domains were chosen from a wide list of possible OMT outcome domains[13], and ordered by their perceived potential health impact for the service user. Potential outcomes were then proposed for each of the domains. The domains and outcomes were subsequently reviewed in the Delphi study by a panel of 757 experts (46% were service users, 40% were female) across 29 countries (Wiessing et al., in press).

The group discussions resulted in a final list of six domains: A. “Treatment” (5 core questions / 2 outcomes), B. “Physical health and risks” (11 core questions / 5 outcomes), C. “Mental health” (2 core questions / 1 outcome), D. “Social functioning” (4 core questions / 3 outcomes), E. “Substance use” (2 core questions / 1 outcome), F. “Quality of Life” (2 core questions / 1 outcome). Together they cover the three areas of the WHO definition of health[14] as well as a range of specific (e.g. overdose, HIV/HCV; substance use) and further issues associated with high-risk opioid use (see Box 1 and Annex 2). Given the risks of including a domain on criminality it was agreed to only include an outcome on ‘legal

[13] From a longer list of possible outcomes (domains, outcomes) based on earlier EUDA publications (Wiessing et al., 2017; Wiessing et al., 2018) and existing instruments e.g. TOP

[14] The preamble to WHO's constitution provides a definition of health: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”

problems' within the Social functioning domain, but not to include an outcome or domain on crime. Also, "Overdose and mortality" was joined with the "Somatic care and risk behaviours" domain into a combined "Physical health and risks" domain. The "Quality of life" domain was moved to the end as to provide an overarching final summary of all other domains and outcomes.

The thirteen outcomes were developed within the final six domains as follows:

Box 1. The final list of 6 domains and 13 outcomes

Domain A 'Treatment'

1. 'Treatment continuity' (4 core questions)
2. 'Treatment satisfaction' (1 core question)

Domain B 'Physical health and risks'

3. 'Physical health' (1 core question)
4. 'Overdose' (2 core questions)
5. 'Injecting drugs' (2 core questions)
6. 'Sharing injection materials' (2 core questions)
7. 'Diseases testing' (4 core questions)

Domain C 'Mental health'

8. 'Mental health' (2 core questions)

Domain D 'Social functioning'

9. 'Social support' (2 core questions)
10. 'Social activities' (1 core question)
11. 'Legal problems'[15] (1 core question)

Domain E 'Substance use'

12. 'Substance use' (2 core questions)

Domain F 'Quality of life'

13. 'Quality of life' (2 core questions)

In total the 13 outcomes are operationalised and measured by 26 core questions. In addition there is a set of further, more detailed, optional questions which can be used in case there is a need for more information on one or more domains, and sufficient time is available (see Annex 2).

We aimed to produce a list of outcome questions that can help the clinician to make the most impact on an individual service user, directly based on the perspective of the service user (service user-centred) and focused on improving health and well-being (rather than abstinence from illicit substances).

From this service user-centred perspective it followed that our list of outcomes should be formatted and presented in a way that an interviewer could directly use in their OMT practice (i.e. as an outcomes

[15] It was decided to not include questions on recent crime, as some participants thought these data can form a risk for the service user, also, and as a consequence, there were doubts about their validity.

questionnaire / interview guide). Thus, in addition to the outcomes we added START and END sections, with information for both interviewer /clinician and service user regarding the interview (see Annex 2).

To ensure action is taken when necessary, in the END section 'action-checks' were included, where the clinician is asked to make explicit what follow-up is needed from the interview, including date of next visit (or proposed time interval to next visit).

Finally, to enable understanding the background risks of the service user as well as group-level analyses to find predictors of the 13 outcomes, we added a BASE (baseline) section with questions that need to be asked only once, i.e. the first time the outcomes questionnaire is used with the service user, and are mostly time invariable (see Annex 2).

The full outline of the outcomes questionnaire is as follows:

5. How do the questions relate to improving care and treatment?

In the initial workshops, the expert group aimed to select the domains, outcomes and related questions that affect the outcome of care and treatment of an individual service user.

The aim was to take a broad approach around the health and wellbeing of a service user, rather than a narrow approach around abstinence and control of substance use.

For example, the group rejected urine analysis as a control tool to detect illicit drug use during treatment and with negative consequences (punishment) for the service user. Rather by focusing on the service user's needs, the idea is to provide an as low as possible 'threshold' to treatment access, retaining service users even if they do not achieve all treatment objectives, with the idea that retention in treatment is a key objective to save lives of people who use opioids, while punishment and control will drive service users away from treatment with important risks to their survival, health and quality of life.

The treatment domain (continuity and service user satisfaction) is key to improving care and treatment with regard to the key outcomes as survival, retention, health and all other outcomes including substance use. Treatment continuity has been found to be a major predictor of survival, whereas monitoring service user satisfaction is central for a service user-centred approach and for retention in treatment.

Given our aim to have a broad health and wellbeing oriented approach to treatment (rather than a more narrow abstinence-oriented approach) it was deemed central to monitor overdose events, HIV and HCV testing, risk behaviour and general health. Thus we decided to follow the WHO definition of health with three domains following the three dimensions in that definition (physical, mental and social health), where the first (physical health) covers a range of adverse health outcomes and diseases testing, the second (mental health) asks about adverse mental issues (stress, depression etc) and the third aims to ask about social functioning of the service user (social support, social activities with others and legal problems).

While substance use is of course a central element of opioid treatment the group chose to not start the interview with it. The idea is that an overly focus on substance use risks narrowing the whole treatment and care to that domain, thus potentially disregarding the broader health and other domains that provide the full picture of the service user's improvement or deterioration. Importantly the expert group does not see (illicit) substance use as the main or sole factor that determines the service user's (lack of) health and wellbeing or the main driving force of their problems. Rather we understand substance use as one factor (both a risk factor and an outcome) within a complex set of circumstances and factors that have led to the deterioration of the service user's quality of life. Thus, it makes less sense to focus on substance use in isolation or to believe that abstinence from illicit opioids will lead to improved treatment outcomes by itself, rather it is important to understand the broader picture of the service users' life problems and see where intervention can help improve their quality of life, which may not necessarily require stopping all illicit drug use. For a truly service user-centred approach, the service user and provider should partner to prioritise their treatment goals, focusing on the needs of the service user.

To improve care and treatment of the service users, it is not enough to just apply this OMT outcomes questionnaire. It is important that the context in which the treatment takes place is adequate and supportive and that the service is organised accordingly (see section "Ten key principles of effective OMT"). For example, referrals may need to be made both to specialist care or general health care of service users in OMT.[16] Also inward referrals, accepting new service users for OMT referred from other services e.g. harm reduction services or (outreach) professionals, should be facilitated as much as possible. For this to succeed it is important that the treatment service sets up and maintains close contact and regular communication and collaboration with those other services, including services that could pose problems for the service users, such as the police. If some of the required health or harm reduction services do not exist or are insufficiently available or accessible, the responsibles for the treatment service should lobby at local and/or national policy level to have such other services implemented and made available for their OMT service users. Ready access and promotion of harm reduction supplies and materials on-site within treatment services is important.

6. How can the OMT outcomes questionnaire be implemented?

The service user outcomes questionnaire can be initiated both for new service users as well as on service users in stable treatment. Ideally, over time, it will increasingly cover all service user-years in treatment from their first treatment week to the current date.

Training on completion of the outcomes questionnaire is essential prior to its implementation. It is strongly recommended first to practise and to test the guidance thoroughly (several times) on colleague professionals who act as a service user, so that all professionals involved understand what is being asked to the service user and what consequences this could have. For example, if a service is not used to doing referrals to other specialist care (e.g. a GP, hospital or a dentist) then it is important that contact and collaboration is sought first with such specialist care, before applying the outcomes questionnaire, to avoid a situation where the interviewer /clinician cannot follow-up on the implications of the questions. As is stated in the START section of the outcomes questionnaire it is essential that the service have general health professionals available, e.g. a nurse and a (visiting) GP.

[16] Some treatment services have fully integrated wrap around care that includes embedded primary and specialty care. For example, integrating HIV treatment on-site in drug treatment services has been shown to result in improved outcomes (Low et al., 2016)

The outcomes questionnaire provides a practical guide on how to structure the interview with a service user, both at the first entry in treatment and repeated after 4 weeks (end of induction) and then in recurrent measurements i.e. ideally / initially every 3 months, but this can be changed to every 6 or even 12 months, depending on the service user.

It is important that the introductory text in the outcomes questionnaire is read by the interviewer /clinician and where required it is read up to the service user, so that the context and conditions (e.g. regarding the possibility to stop the interview at any time) remain clear to the service user. It is very important that the service user understands the importance of monitoring these outcomes over time so that the clinician can optimise the treatment for them.

At the first treatment visit it is suggested to do at least the START, CORE, BASE and END questions. Then, if any of the CORE outcomes suggest a problem in any domain it is recommended to take the OPT (optional) questions for that domain either at the same visit, or at the next visit, but then preferably soon after that first visit (e.g. in the same week). If the service also uses the TDI protocol to collect data it is recommended to do that first (e.g. on the first day[17]) then to apply the OPTIMUS outcomes questionnaire e.g. on the second and third day. If there is more time the interviewer /clinician and service user can decide together to do more OPT questions or even all of them. If necessary the instrument can be used over two or three visits, preferably as early as possible / during admission (but making sure that the START, BASE, CORE and END questions are all asked the first time).

At the end of the END section questions the interviewer /clinician should indicate what is the recommended follow-up period or what is the planned date for the next treatment visit where the outcomes questionnaire will again be used. The first repeat use can for example be once the induction period is finished and the service user is on stable treatment, and after that every 3, 6 or even 12 months, depending on how problematic the service user is. However, even when a longer follow-up interval is preferred, it is recommended to initially use the outcomes questionnaire every 3 months (e.g. in the first year of treatment) and only then to gradually move to a 6 month or 12 month interval depending on the service user's situation.

To follow a service user over time and evaluate their outcomes ideally the interviewer /clinician has all the previous data directly available when doing a new interview (e.g. both in tabular and graphical format). For this it would be necessary to implement a simple data collection and analysis tool, e.g. in MS Excel, where the interviewer /clinician enters the data while doing the interview and directly sees the new data point in the tables and figures that show all the results and previous answers from this service user over time. This ideally means avoiding data entry on paper (paper forms) and rather implementing the outcomes questionnaire in a suitable data entry format and using a pc or laptop or tablet during the interview for data recording. This may include the possibility for the service user to provide self-administered answers directly into the laptop or tablet together with the interviewer /clinician. It is very important when developing such a data entry and analysis system to avoid any risk of data loss by implementing direct 'live' backups, e.g. into the cloud, and a stringent data safety procedure to avoid personal data of the service user being seen by non-authorised staff or be accessible from outside the service.[18]

Applying this guidance may require changing some of the ways the service is working. For example, giving more attention to all health and social aspects of a service user (rather than only their substance

[17] See a generic definition of start of treatment in the TDI protocol, however, in the present guidance start of OMT is defined as date of first prescription of OMT medication.
[18] See further ethical considerations in the TDI protocol, page 62

use problems) requires more time and other specialists to be involved. In countries where this health-centred approach is standard practice the actual interviews and medication dispensing to service users are not all done by medical doctors /addiction specialists, but rather by (social care) nurses and other support staff, under the supervision of the medical doctor or specialist. This often allows larger numbers of service users to be frequently seen, even up to over 1000 per day per service[19], as the main and regular service user contact is limited to medication dispensing (just one or a few minutes per service user) and further health and social care is organised by referral to other specialist services. This should result in a high proportion of PWUO being in continuous (maintenance) opioid treatment, removing waiting lists and increasing population coverage, thus (strongly) reducing mortality and health problems.

[19] E.g. the methadone bus of the non-governmental association 'Ares do Pinhal' in the Lisbon area (Portugal) sees up to 1300 service users on a daily basis. https://linklist.bio/AssociacaoAresdoPinhal

Figure 1. Guide to using the outcomes questionnaire

7. Data management and analysis

It is highly recommended to not only apply the instrument and analyse data at the individual service user level but to analyse the data also at group level. The aim of group level analysis is to study how the service user group changes over time and to assess which outcomes are showing improvements and which outcomes may need more attention. This analysis can also help to understand what factors are associated with positive or negative outcomes. This usually requires strong statistical expertise therefore may best be done in collaboration with or by (academic) staff with experience in longitudinal data analysis. Some points need to be taken into account even before starting the data collection, else it will be almost impossible to correct them later. These include:

1. Make sure an informed consent is recorded at the first visit of each service user, where the service user agrees that their data may be used in anonymised form for future data analyses that will measure changes in outcomes over time.
2. Make sure that service users are uniquely identifiable not just at the treatment service (where usually names are available) but ideally also between treatment services in the same region and even across the whole country. This allows in future data analyses to identify service users that left one service and entered another and estimate overall treatment participation over time (Nordt et al., 2018). It is of utmost importance to use a safe identification system where data are anonymised and service users are still identifiable. Service users need to be identifiable so that they may be tracked across time and treatment sites within your country. Some countries have a unique identifier but many countries do not. If this is the case then a simple identifier can be made using: birth date, sex (at birth) and the initial or second letters of first and last name,and a truncated postcode.[20,21,22,23]
3. It is important to record the date of treatment admission for each service user. We recommend using the date of first medication taken (or if unknown: prescribed) as the actual treatment start date. This should be recorded separately from the date of first treatment demand and the date of first interview with the OPTIMUS outcomes questionnaire (see question START-1 in the START section).
4. It is important to record the date of last dose of medications taken (treatment cessation) for service users who leave treatment (or, if unknown, date last prescribed), as well as the reason for leaving treatment. If a service user has disappeared from treatment then record the last

[20] Using birth date, sex (at birth) and the initial or second letters of first and last name, potentially with a geographic locator, has been shown to be an adequate, albeit imprecise mechanism for case-linkage between datasets in previous national treatment registry cohort studies (Pierce et al, 2015; Pierce et al, 2016). Roberts et al (2020) describe a straightforward, four stage, deterministic matching protocol applied to treatment registry data, based on combinations of date of birth, truncated postcode/zip code, sex, ethnicity, and service users' primary care centre that enhances linkage accuracy. However, optimal linkage is achieved using probabilistic methods (Emanorado et al, 2019) that can be applied to combinations of 'identifying' data items, for which open source code is available (https://github.com/kosukeimai/fastLink). These have been developed further to provide fast linkage at scale (https://www.gov.uk/government/publications/joined-up-data-in-government-the-future-of-data-linking-methods/splink-mojs-open-source-library-for-probabilistic-record-linkage-at-scale), and open source code is available for this (https://github.com/moj-analytical-services/splink/).

[21] In Portugal the Ministry of Health codes individuals as: date of birth (DD/MM/YYYY) first two consonants of the first name and first 3 consonants of the surname; for the council of Lisbon the same method is used but with date of birth coming at the end.

[22] In North Macedonia, all services that have an anonymous code for the client use: first three letters of the client's mother's name, day of birth, first three letters of the client's name and month of birth. For example: MAR22LIL10 (from Maria, Liliana and October 22)

[23] See a proposal from the Czech Republic, Denmark and Norway in (Gabrhelík et al., 2021).

known date that the service user used their medication (or date last prescribed).[24]

5. It is important to record any interruptions in the treatment (date of last use or prescription / start of interruption and date of first use or prescription / end of interruption), e.g. defined as of 'at least two days' if dispensing is recorded daily, or 'one prescription' if prescriptions are recorded e.g. every two weeks.
6. It is important to record what medication the service user is using and at what dosage, both at each follow-up and if medication or dosage change.
7. We recommend also recording if the service user receives psychosocial support (with the date - or start and end dates - and what type of support is given) as well as to record any referrals to other services and/or care (with dates and specification of the referral including if the service user was admitted to that service and received the intended care, if possible, e.g. this information can be asked in a follow-up visit or obtained directly from the referred service, if reasonably feasible - e.g. by setting up an online or email service user referral checking system with other services). It should however be kept in mind that referrals are not ideal and a far better approach is having the key services available in-house ('one-stop treatment').

Ideally it might be possible to develop a separate data template with standardised variable names and formats for these data so that it will be possible to estimate treatment retention and participation in a comparable way between regions and countries (Nordt et al., 2018).

8. Final recommendations for practice

The Opioid Maintenance Treatment Outcomes Group recommends:

1. Using a standardised approach to opioid maintenance treatment outcomes evaluation, preferably using a wide range of relevant domains, including key health, social and quality of life outcomes, as proposed here. (see Annex 2)

2. Ensuring that relevant health and social services are available, preferably in-house ('one stop shop') e.g. by nurse and (visiting) physician and/or through an efficient system of referrals with service user follow-up.

3. Treatment practice is service user-centred, not judgemental nor stigmatising, and evidence-based (e.g. regarding medication choice and dosage and regarding uninterrupted maintenance treatment where service user satisfaction is an important element. (see section "Ten key principles of effective OMT").

[24] See a more generic definition of end of treatment in the TDI protocol, page 31. For this guidance we recommend focusing on the date of last known use (or prescription) of OMT medication.

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10. Annexes

Annex 1. The OPTIMUS* Study Group

As of 23 September 2025

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*OPTIMUS - OPioid Treatment outcomes Interview for Maintenance medication USers

Annex 2. The OMT Outcomes Questionnaire (OMT Guidance Part B)

For English version see here

Annex 3. Treatment outcomes reported by European countries (TDI 2018)[25]

Questions emailed to National TDI Experts prior to the workshop (all 28 EU countries plus Norway, Turkey and Kazakhstan):

1. What type of treatment outcome assessments exist in your country (ongoing formal monitoring, ad hoc academic study, informal medical assessment etc) Please give some further detail in a few sentences
2. What indicators do you think are the most important in order to assess overall improvement of clients in opioid substitution treatment?
3. Are these indicators different in other types of treatment for opioid users?
4. Are these indicators different in people treated for other drugs?
5. What methods are you using in your country to monitor these indicators, or what methods would you think would be best to use?

Seven out of 31 countries responded, reporting on their treatment monitoring outcomes used:

- Estonia: Tx interruptions, Work/education, Crime, Tx duration, Relapse
- Croatia: Tx plan, Health, Infectious Diseases, Risk behaviour, Mortality
- Hungary: CAST+SDS, Health locus of control, Life management, Self-reflection, self reported abstinence
- Kazachstan: Mortality, Life expectancy, Social /work adaptation
- Luxembourg: Current use of drugs, addiction level, craving, social cognitive factors such as (abstinence & relapse) self-efficacy and attitude towards abstinence, social support and social norms, intrinsic and extrinsic motivation, intention to remain abstinent, level of depression/anxiety, period of abstinence, relapse & lapses, crime, quality of life, co morbidity/health, socio-economic factors (social and professional re-integration), infectious diseases (notably HCV re-infections), health-related problems related with IDU
- Latvia: Substance use outside Tx, Mortality
- Netherlands: Always combination of outcomes, Quality of Life and Social functioning and client satisfaction (+ a much longer /more detailed list of variables)

[25] Written reports provided in preparation for the 2018 EMCDDA-TDI workshop responding to the questions listed above. See here the full TDI workshop report (L Wiessing, 2018).

Summary of responses as presented at the workshop

1. Many different outcomes, no common core set visible, variation between more medical or more social outcomes being used
2. Outcomes generally not different for other opioid treatment, or for other drugs

Few countries seem to have Tx outcome monitoring in place, and some report serious problems in data quality (e.g. only positive outcomes being recorded)

Annex 4. Delphi study protocol and panel survey (round 2)

See the full study protocol with the round 2 panel survey here

Delphi panel composition

Each participating country will strive to recruit (8-)10 professionals and (8-)10 OMT service users. Each group will as much as possible be balanced by gender.

Professionals will include a minimum of:

- 3 OMT medical professionals (e.g. psychiatrist, addiction doctor, general practitioner)
- 3 OMT health professionals (e.g. social [care] worker, councillor, nurse, outreach worker, psychologist, pharmacist)
- 1 public health specialist
- 1 prison health professional

Professionals will also:

- be working in their field at least 5 years
- cover different sectors if applicable in the country (e.g. public and private)
- preferably working directly with clients (with some exceptions, e.g. public health specialist), and not just in the management of the OMT organisation

service users will be:

- currently in OMT
- at least 18 years old
- balanced with regard to time in OMT (about half less than 2 years in OMT and half 2 years or more in OMT)

Annex 5. List of abbreviations

BASE	Section with baseline questions of the outcomes questionnaire
CORE	Core questions of the outcomes questionnaire
EMCDDA	European Monitoring Centre for Drugs and Drug addiction (now EUDA)
END	End section of the outcomes questionnaire
EUDA	European Union Drugs Agency (formerly EMCDDA)
GP	General practitioner
LGBTQI+	Lesbian, gay, bisexual, transgender, queer, and intersex people
OAT	Opioid Agonist Treatment[26]
OMT	Opioid Maintenance Treatment
OPT	Optional questions of the outcomes questionnaire
PWUO	People Who Use Opioids
START	Start section of the outcomes questionnaire
TDI	Treatment Demand Indicator[27]
TOP	Treatment Outcomes Profile[28]

[26] It was decided initially to follow the new WHO acronym 'OAMT' ('Opioid Agonist Maintenance Treatment', which has replaced the standard term OST/'Opioid Substitution Treatment' after the latter was criticised for being 'stigmatising' (A.Verster WHO, written communication 2022). For this guidance, OAMT was then simplified to OMT, a term that has been used frequently in the literature. In the core and optional outcome questions (see Annex 2) acronyms were avoided and replaced by 'opioid treatment'. (Ideally they might be used in a service user-specific and medication-specific way, e.g. as in 'your methadone/buprenorphine/etc treatment'.) OMT was thought to be more service user-friendly than OAMT by avoiding the technical term 'agonist', and there was a perceived redundancy between the 'A' and the 'M' in OAMT, given there exists no effective long-term antagonist treatment (Jarvis et al. 2018, Minozzi et al. 2011). The term OAT has been strongly promoted recently, but has serious shortcomings, including that it does not limit to live-saving long-term opioid treatment (Sordo et al. 2017) but includes short-term agonist treatments which can result in a high mortality risk. Other acronyms in use, such as MAT (medically assisted treatment) or MOUD (medication for opioid use disorder), were thought to be even weaker in this respect as they include antagonist treatments, resulting in a high risk of dropout with associated high overdose/mortality risk and without evidence of effectiveness (Jarvis et al. 2018, Minozzi et al. 2011). Thus they combine even more divergent treatment approaches, resulting in an unclear definition of opioid treatment. Although the term OST, until recently used by WHO for long-term opioid maintenance treatments and linked to a solid evidence-base that OST is life-saving, has been criticised for being 'stigmatising', it was used throughout the first Delphi round for this guidance ('OST' appeared 27 times in the survey, 'substitution' 7 times, of which 3 times in the actual outcomes to be evaluated). In that round, in which the 477 panel members were asked for comments on the draft questions and outcomes, not one comment stated that 'OST' or 'substitution' are potentially stigmatising, out of a total of 1049 open comments received. These data suggest that the 'stigmatising' aspect of OST is very limited in the European region, where long-term opioid treatment is the norm. The word 'substitution' being perceived as stigmatising may be mainly an issue in countries where the norm is to expect full abstinence ('recovery') from a service user (Volkow 2014) including from medication, despite this is extremely difficult to achieve for the vast majority of service users and puts them at high risk of relapse, overdose and death.

[27] https://www.euda.europa.eu/publications/manuals/tdi-protocol-3.0

[28] --

WHO World Health Organisation