



# Opioid Agonist Maintenance Treatment Outcomes—The OPTIMUS International Consensus Towards Evidence-Based and Patient-Centred Care, an Interim Report

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## Mortality due to Non-medical Opioid Use Is High and Varies Geographically

Non-medical opioid use and opioid use disorders continue to result in an unacceptably large number of deaths. Worldwide, about 600,000 deaths were attributable to drug use in 2019. Close to 80% of these deaths were related to opioids, with about 25% of those deaths caused by opioid overdose (UNODC, 2022; World Health Organization, 2023; Vos et al., 2020). Mortality rates due to overdose (direct drug-related deaths) vary greatly between countries and regions, in part due to underlying variations in the prevalence of high-risk drug use and the toxicity of the drug supply (e.g. the integration/contamination of fentanyl into the heroin and counterfeit prescription pill supply) (Mattson et al., 2021; Degenhardt et al., 2019; Millar & McAuley, 2017). For example, while the European Union reported 14.8 deaths due to drug overdose per 1 million population aged 15–64 in 2019, the USA reported an age-adjusted mortality of 216 per 1 million population for the same age group in the same year (UNODC, 2022).

## A Higher Uptake of Evidence-Based OMT Could Save Lives and Improve Health

Many opioid-related deaths are preventable, and long-term uninterrupted opioid agonist maintenance treatment (OMT) would need to play a far greater role in this. There is

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compelling evidence that uninterrupted and adequately dosed OMT (such as with methadone, buprenorphine and slow-release morphine) strongly reduces (with up to 3–6 times) the risk of death in people who use opioids (PWUO) (McAuley et al., 2023; Santo et al., 2021; Bogdanowicz et al., 2018; Sordo et al., 2017; Pierce et al., 2016; Mathers et al., 2013; Mattick et al., 2009; Bao et al., 2009; Brugal et al., 2005). However, where data are available, they suggest that many countries still have low, or even near-zero, coverage of OMT among PWUO, over two decades since the EMCDDA developed harm reduction and OMT coverage metrics that are now widely used (Harm Reduction International, 2022; Larney et al., 2017; World Health Organization et al., 2012; Mathers et al., 2010; Wiessing et al., 2009; European Monitoring Centre for Drugs and Drug Addiction, 2006, 2007; Wiessing et al., 2000). In those countries, important reductions in opioid-related mortality may be achievable, by increasing OMT coverage to internationally recommended levels of 40–50% or higher (European Monitoring Centre for Drugs and Drug Addiction, 2023; The Global Fund, 2022; UNAIDS, 2021; World Health Organization et al., 2012). Further mortality reductions might be reached by strengthening additional health and social interventions (Levengood et al., 2021; Razaghizad et al., 2021; Wiessing et al., 2021; van Draanen et al., 2020; Katzman et al., 2020).

OMT not only prevents key causes of death, including overdose, suicide, HIV, hepatitis B and C virus infections and injuries (Ferraro et al., 2021; Pitkänen et al., 2020; Degenhardt et al., 2019; Fraser et al., 2018; Platt et al., 2018; Sordo et al., 2017; Mattick et al., 2014; Gowing et al., 2013; Mathers et al., 2013; Allen et al., 2012; Deacon et al., 2012; MacArthur et al., 2012; World Health Organization et al., 2009; Metzger et al., 1993), but also improves health-related quality of life and reduces illicit drug use and the severity of opioid use disorder (Feelemeyer et al., 2014; Mattick et al., 2014; Farré et al., 2002; Torrens et al., 1999). It may further reduce depression (Namchuk et al., 2022; Mohammadi et al., 2020) and decrease drug-related offences and incarceration rates (Carrieri et al., 2017; Sun et al., 2015; Marsch, 1998), while overall being cost-saving (Degenhardt et al., 2019; World Health Organization, 2005). OMT has been shown to be more effective in reducing adverse events in PWUO than short-term detoxification or psychological treatment (Nielsen et al., 2022; Wild et al., 2021; Rice, 2020; Friedmann & Schwartz, 2012). Also, combining syringe programs or antiretroviral treatment with OMT has been shown to be highly effective (Platt et al., 2018; Roux et al., 2009). However, in 2021, only four countries in Europe had met the WHO-recommended coverage of at least 200 syringes per injecting user per year and 40% of PWUO in OMT (European Monitoring Centre for Drugs and Drug Addiction, 2023). Thus, increasing OMT coverage to recommended levels, or higher, in countries where these are not yet being reached would likely have a positive impact on PWUO reaching far beyond reducing mortality.

## **A Lack of Consensus and Confusion in Terminology Limit OMT Uptake**

A good understanding of the full potential impact of high-coverage OMT on the morbidity and mortality of PWUO is essential for achieving recommended levels of coverage (World Health Organization et al., 2012), including in specific subgroups, such as women or migrants (Nordt et al., 2018). However, despite the abundance of evidence, this understanding is often still partial and lacks consensus on key issues, both in the scientific literature and in policy and practice, thereby seriously hampering wider implementation of OMT (Torrens et al., 2013; Schackman, 2010).

There is surprisingly little agreement in the scientific literature on what constitutes successful treatment of opioid disorder and what are the key indicators to evaluate patients over time (Wiessing et al., 2018). Different studies use different outcome domains and indicators to assess patient outcomes, ranging from a narrow focus on abstinence-based recovery to a broader (public health or harm reduction-oriented) approach, including health and survival and social and quality of life outcomes (Rosenberg et al., 2020; Wiessing et al., 2018). Importantly, few published opioid use disorder treatment outcome studies have considered the key health outcomes that dominate the global burden of disease due to opioid use, such as non-fatal overdose and mortality, HIV/HCV infection and their associated risk behaviours (James et al., 2018; Wiessing et al., 2018).

There is no global consensus either on what constitutes successful drug policy or treatment practice. A decades-long emphasis on repression and supply reduction is only recently showing a possible first pivot towards evidence-based public health outcomes, while national drug policies appear not always to be evidence-based either (Interlandi, 2023; Fordham, 2022; Hamilton et al., 2022; Burki, 2019; Global Commission on Drug Policy, 2019; American Hospital Association—Legislative Advisory, 2018; Radimecký, 2007; World Health Organization, 2005). In treatment practice, even when agonist medication such as methadone or buprenorphine is used, it is too often tapered and discontinued in detoxification or residential treatments (Friedmann & Schwartz, 2012). This, despite the evidence that treatment interruptions are a major risk factor for overdose and death, and, conversely, long-term uninterrupted OMT is life-saving (McAuley et al., 2023; Santo et al., 2021; O'Connor et al., 2020; Sordo et al., 2017; Mathers et al., 2013; Mattick et al., 2009). Moreover, there is evidence that clinical practices of OMT delivery (e.g. urine screening, dosage decision-making and daily dispensing) and an emphasis on clinical outcomes (e.g. abstinence) rather than patients' preferences and perceptions may not always constitute a patient-centred practice and may impose substantial barriers to OMT engagement (Frank, 2021; Woo et al., 2017; Harris & McElrath, 2012; Anstice et al., 2009), while mental health and quality of life domains are often not addressed (Javakhishvili et al., 2021; Eurasian Harm Reduction Association, 2020).

The lack of consensus extends to the terminology being used, creating confusion and undermining the ability to even discuss the issues at stake. Historically clear WHO-endorsed and evidence-based concepts such as OST (opioid substitution treatment) or OMT are now being replaced by concepts and acronyms that combine opposite treatment approaches within one and the same term, rendering them imprecise and meaningless with regard to their life-saving properties. For example, long-term maintenance or substitution treatments with agonist medication which are evidence-based lifesaving (e.g. Sordo et al., 2017) are now often combined with short-term agonist detoxification approaches in the term 'opioid agonist treatment' (OAT), apparently following abstinence-oriented and non-evidence based arguments (Samet & Fiellin, 2015; Bøg et al., 2017). Similarly, treatments with live-saving long-term agonist medication are put together with potentially ineffective or even life-threatening antagonist medication treatments (e.g. with naltrexone) in the terms 'medication for opioid disorder' (MOUD) or 'medication assisted treatment' (MAT) (Jarvis et al., 2018; Sordo et al., 2017; Minozzi et al., 2011). (For more detail and empirical evidence from our work regarding opioid disorder treatment terminology, see the Online appendix: 'Document 1a. OMT guidance Part A', p21).

## The OPTIMUS International Consensus on OMT Outcomes

Here we report the rationale and the need for, as well as the protocol and preliminary results of, an ongoing international consensus study to define key outcomes for the monitoring of patients on OMT (The OPTIMUS study: OPioid Treatment outcomes Interview for Maintenance medication USers). We aim to promote international consensus on evidence-based treatment policies and treatment outcome indicators for PWUO and OMT by bringing together experts (professionals and patients) from as many countries as possible, including from outside Europe. We focus on patient-reported outcomes and present a tool that aims to directly support clinical practice, encouraging a non-stigmatising patient-centred approach within an enabling and positive patient–physician relationship (Marchand et al., 2020; Seabra et al., 2018; Lions et al., 2014). With this work, we hope to contribute to a much-needed global paradigm shift towards evidence-based and patient-centred opioid treatment, non-abstinence-based recovery and increased survival, health and quality of life of PWUO.

We present the early version (‘version 1.0’) of a clinical tool to monitor and evaluate OMT outcomes based on patient-reported results (see the Online appendix, Annex 1, part B). The tool centres on a set of 26 core questions for a patient interview, organised in 6 domains and 13 indicators (see Box 1), which we suggest taking once every three months, and depending on patient needs. It functions simultaneously as an interview guide and a patient questionnaire or clinical form. Our tool is being developed by an international group of 110 OMT experts from 32—mostly European—countries (6 outside Europe: 2 from North-America, 3 from West Asia and 1 from Oceania), including people with lived OMT experience. It incorporates 1049 open comments from an international panel of an additional 477 OMT experts from 26 countries, received during the first round (out of 2) of an on-going Delphi-method consensus study.

### Box 1 The consensus list of 6 domains and 13 indicators (totalling 26 core questions)\*

#### 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 screening’  
(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’  
(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)

\*This is work in progress and the domains and indicators may still be subject to change. See full details of the core and optional questions in the Online appendix: ‘Document 1b. OMT guidance Part B’

## OPTIMUS Delphi Study Preparation and Methods

The EMCDDA has a long-standing collaboration with, and organises an annual meeting of, country representative treatment experts from the EU and neighbouring countries, to discuss drug treatment patient monitoring. (The Treatment Demand Indicator—TDI, a descriptive monitoring of patients at treatment entry for substance use disorders (European Monitoring Centre for Drugs and Drug Addiction, 2012)). Prior to the Delphi study, an email survey was sent to all TDI collaborating country experts asking them to describe any existing substance disorder treatment outcomes monitoring in their country (Wiessing, 2018). Out of 31 countries (EU-28, plus Norway, Turkey and Kazakhstan), only 7 responded with the requested information, suggesting (a) limited existence of treatment outcomes monitoring systems in these countries and, based on the 7 responses, (b) a wide variation in indicators and methods used (similar to the literature review findings (Wiessing et al., 2018) mentioned above). These results were confirmed in a subsequent workshop with 17 countries participating (15 EU countries plus Kazakhstan and Uzbekistan) during the 2018 TDI expert meeting (Wiessing, 2018). Workshop participants were asked to prioritise domains and indicators taking account of the need for international consensus treatment outcomes monitoring with a focus on (public) health outcomes. This resulted in a ‘First priority OMT health impact indicators’ list: (1) overdose and mortality/causes (outcome indicator), (2) infectious diseases (hepatitis C) test and treat (outcome/service indicator), (3) OMT waiting time and coverage/treatment participation (affordable and including prisons) (service indicator), and a list of ‘Second priority OMT health impact indicators’, (4) treatment retention (outcome/service indicator), (5) NSP coverage of PWID population including in prisons (service indicator) and (6) quality of life /health (outcome indicator) (Wiessing, 2018). To follow-up on and further develop the results of the TDI workshop, a two-day expert meeting was held at the EMCDDA in Lisbon in early 2019, with 13 treatment experts from ten countries participating (a further 8 experts from 4 more countries—one of them with lived OMT patient experience—could not attend but contributed by email) (Wiessing, 2019). During this meeting, the results of the TDI workshop were discussed and further developed, and it was agreed that a Delphi study was needed with a wider panel, composed of both professionals and patients, to evaluate and increase the representativeness and legitimacy of the findings (Wiessing, 2019).

The expert group continued working during 2019–2020 in weekly online meetings and group emails to further define the domains and indicators and prepare the Delphi study (group emails and meeting minutes are available on request). It was decided that indicators would be limited to patient-reported outcomes to maximise their relevance for patients (e.g. dropping service-level indicators, which have been covered elsewhere (HRI, 2022; Larney et al., 2017; Wiessing et al., 2017)) and that the Delphi study surveys would be translated to the national languages. A first version of domains and indicators was finished for evaluation in the Delphi study and a study protocol was developed covering the Delphi study methods and with additional detailed instructions regarding translations and panel recruitment (see Annex 2 in the Online appendix) and medical-ethical clearances were obtained. During this period, the expert group expanded and eventually covered 27 countries (at

round 1 of the Delphi study). The additional countries and experts were recruited via formal invitations to the TDI expert network and through professional contacts of the existing expert group.

During 2020–2021, the Delphi panel members were invited to fill out the round 1 survey following the protocol (see Annex 2 in the Online appendix). Each country strived to invite (8–)10 professionals and (8–)10 OMT patients. Each of these two groups was to be as much as possible balanced by gender. As far as possible, professionals included at least 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 and 1 prison health professional. Professionals would also, as far as possible, 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. Patients were those currently in OMT, at least 18 years old, and were balanced with regard to time in OMT (about half of them less than 2 years in OMT and half of them 2 years or more in OMT). We comply with guidance on conducting and reporting Delphi studies in palliative care (Jünger et al., 2017) (see Annex 3 in the Online appendix).

## Interim Results and Discussion

The final list of 26 countries participating in round 1 of the survey was Albania, Belgium, Bosnia and Herzegovina, Canada, Cyprus, Czechia, Denmark, Finland, France, Georgia, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, the Netherlands, North Macedonia, Palestine, Poland, Portugal, Slovakia, Spain, Switzerland, the UK and Ukraine. In total, the expert group recruited 477 panel members in round 1, with about half of those being patients ( $n=224$ , 47%) while 193 professionals (40.5%) indicated working directly with OMT patients and 60 (12.6%) working in an area related to OMT. Support for the domains and indicators was strong (average score across all 13 indicators 5.06 out of 6 (range 4.90–5.26), average SD 1.04 (range 0.93–1.31), alpha coefficient 0.90). However, based on the 1049 open comments received, the indicators were further revised, and optional questions were added (see Box 1 and Annex 1). The indicators are currently being re-evaluated in round 2 of the Delphi study (indicator questions were extensively revised but domains remained unchanged between round 1 and round 2).

Initial feasibility testing on a limited number ( $n=20$ ) of patients in four countries suggests the tool is well accepted by both clinician and patient and is deemed balanced, feasible and very useful (interview time: without optional questions: median 14 min, interquartile range (IQR) 11.5–17.5 min; with optional questions: median 27 min, IQR 22–31 min). In some cases, patients found the interview a bit too long, and in other cases, the clinician said a longer interview was actually helpful, allowing for more discussion on interventions (Sharma, 2022).

Other studies have proposed indicators to evaluate outcomes of drug treatment (Stirling et al., 2023; Karnik et al., 2022; World Health Organization, 2020; Marsden et al., 2008). However, these have been developed for specific national contexts and are not based on an international consensus process. Also, most of these studies are not focused on PWUO /OMT (Stirling et al., 2023; World Health Organization, 2020; Marsden et al., 2008), in some cases resulting in relatively generic and unspecific indicators for this key group of patients. Some studies combine patient-level and system-level indicators, or indicators that require additional

complex methodology (e.g. mortality), making them difficult to apply in, or even irrelevant for, clinical practice (Stirling et al., 2023; Karnik et al., 2022). To the best of our knowledge, we present the first international consensus protocol for treating opioid use disorders that is evidence-based (i.e. focused on OMT as the evidence-based treatment of choice), fully patient-centred (i.e. based on patient-reported data) and directly aimed at supporting clinical practice in monitoring OMT outcomes in PWUO, while including key (public) health outcomes that have so far scarcely been covered in treatment outcome studies (Wiessing et al., 2018). Although we here present a patient-centred set of treatment outcome indicators for use in clinical practice, we strongly support additional system- or aggregate-level monitoring to be carried out in parallel, using both patient-reported outcome measures, service data and observational studies, and combining these using formalised implementation science methods (Wiessing et al., 2017; Lambdin et al., 2015; Schackman, 2010; Silverman, 2009).

An important limitation of the present report is that it presents preliminary results of ongoing, unfinished work. Our draft consensus guidance has only been evaluated in one survey round with the Delphi panel; however, we found a very high level of agreement already and received mostly very supportive open comments. These resulted in the addition of optional questions, which may be a strength (adding depth) but also made the tool seem larger—although it should be noted that the optional questions will usually be partly or mostly omitted as they are only recommended for domains where the core questions suggest a problem exists. A further limitation is that the draft tool has so far been feasibility-tested on only a small number of patients ( $n=20$ ). However, these first feasibility testing results are highly encouraging, with very positive feedback from both clinicians and patients, and suggesting that the time investment (about 15 min for core questions only and about 30 min when including also optional questions) is feasible in clinical practice, if only done once every three months or, depending on the patient, even less frequently. Based on responses received so far in round 2 of the Delphi study ( $n=171$  by 6 November 2023), levels of agreement are as high as in round 1 (data not shown) and we do not foresee important further changes to the tool, until after doing more extensive feasibility and validity testing studies with patients.

With this preliminary interim report, we aim to make the first version of our tool available in the scientific domain, to potentially already start influencing treatment policies for saving and improving the lives of PWUO. Readers of this interim report are welcome to translate the tool into their own language for their own use, preferably after contacting us and following our agreed translation protocol, to test it together with OMT patients in their own local or national context, and to join our study group and/or let us know their experiences.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s11469-023-01213-9>.

**Acknowledgements** See Annex 1 in online appendix. OPTIMUS: OPioid Treatment outcomes Interview for Maintenance medication USers (see list of names of the full study group in Annex 1, Part A of the online appendix)

**Author Contribution** LW—coordination project, drafting consensus protocol, drafting manuscript. All authors—participation in live and online consensus meetings, comments on multiple draft versions of the consensus protocol, comments on multiple draft versions of this manuscript, and approval of the final version.

**Data Availability** The data presented in this study are available on request from the corresponding author.

## Declarations

**Conflict of Interest** The authors declare no competing interests.

**Ethical approval** Ethical approval was obtained on 20 May 2021 from the Ethical Board of the Czech National Monitoring Centre for Drugs and Addictions, Prague, Czechia, for all participating countries. In some countries additional local approval was required: 1) For Spain, approval was obtained on 23 July 2021 from the “Comité de Ética de la Investigación con medicamentos del Parc de Salut MAR”, Barcelona, Spain. 2) For Switzerland, on 17 December 2021 the Swiss Kantonale Ethikkommission in Zurich reviewed the protocol and decided the study was exempt from ethical approval (due to only asking opinions). 3) For Cyprus, on 31 January 2022 ethical approval was obtained. 4) For Canada, on 1 February 2022 also ethical approval was obtained. For further details and original documents see Annex 2 in the online appendix, section 2.17 “Ethical Approvals”

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