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ORIGINAL ARTICLE

The OPTIMUS International Consensus Guidance for Monitoring User-Reported Outcomes of Opioid Maintenance Treatment: a Delphi Study

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Abstract

Opioid use disorder is a major cause of drug-related harm and mortality. These can be reduced by expanded access to evidence-based and highly effective opioid agonist maintenance treatment or therapy (OMT). There is a lack of consensus on how to assess opioid use disorder treatment outcomes, and key health outcomes are often omitted. We report the results of a Delphi study to produce service user- and public health–centred international consensus guidance for OMT outcomes monitoring. An international group of 110 substance use specialists in 32 countries, including service providers, researchers and people with lived experience of OMT, produced draft guidance over multiple meetings. The guidance includes a service user-reported OMT outcomes questionnaire, based on 26 core questions, plus optional questions, in six domains (treatment, physical health, mental health, social functioning, substance use, quality of life). A Delphi panel of 757 OMT professionals and service users (46%) from 29 countries, of which 40% were female, reviewed the questionnaire over two survey rounds, supporting and improving it (round 2 mean agreement score on a 1-6 Likert scale: 5.2; 95%CI 5.1–5.3). By focusing on service user–reported and public health–centred outcomes of OMT, the OPTIMUS consensus guidance aims

OPTIMUS: OPioid Treatment outcomes Interview for Maintenance medication USers (See list of names of the full study group in the online appendix, Annex 1a, p17).

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to facilitate the communication between service providers and service users and improve the quality of care and the survival, health and quality of life of OMT service users.

Keywords Opioid Agonist Maintenance Therapy (OMT) · Treatment outcomes · Monitoring · People who use drugs (PWUD) · People who use opioids (PWUO) · Public health · Substance Use · Overdose · Lived Experience · Delphi

Background

Non-medical opioid use and opioid use disorders are the main drivers of drug-related disease and death globally. 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 overdose (UNODC, 2022; WHO, 2023). Opioid use disorders also accounted for the majority (71%) of the 18 million healthy years of life lost owing to premature death and disability in 2019 (UNODC, 2022).

High retention in adequately dosed opioid agonist maintenance treatment (OMT), such as with methadone, buprenorphine and oral slow-release morphine, strongly reduces (by a factor of 3 to 6) the risk of death in people using opioids (PWUO) (Bao et al., 2009; Bogdanowicz et al., 2018; Brugal et al., 2005; Mathers et al., 2013; Mattick et al., 2009; McAuley et al., 2023; Pierce et al., 2016; Santo et al., 2021; Sordo et al., 2017), in addition to increasing their health (physical, mental, social) and quality of life (Javakhishvili et al., 2021; EMCDDA 2023; Harm Reduction International, 2022; Larney et al., 2017). However, many countries, even in Europe, still have low or negligible coverage of OMT among PWUOs, this being inconsistent with evidence-based practice. Furthermore, many programs continue to have medication shortages, restricted access to take-home doses or treatment compliance monitoring. Some services monitor adherence to OMT by urine or saliva metabolite analysis, without any evidence that this improves treatment outcomes (McEachern et al., 2019). On the contrary, drug testing is often linked to punitive measures which may reinforce stigma and lead to treatment failure due to not responding to service users' experience and needs (Anstice et al., 2009; Davis et al., 2020; Frank, 2021; Harris & McElrath, 2012; Kelley et al., 2022; Woo et al., 2017).

There is still a lack of consensus in the scientific literature about which outcomes are the most useful to evaluate the treatment of opioid use disorder. A systematic review of 27 observational opioid use disorder treatment outcome studies found large variation in outcome domains and indicators used, with just two of the eight identified outcome domains being used by more than half of all studies (Wiessing et al., 2018). Importantly, the review also found that few of the studies included key (public) health outcomes, such as non-fatal overdose, infectious diseases, injecting and sexual health risks, in their patient assessments. This reflects fundamental differences in opinion on what are the main objectives of opioid use disorder treatment, mirroring a similar confusion and lack of consensus in national drug policies (Wiessing et al., 2023). Thus, while many non-evidence–based treatment approaches are aimed at to reaching recovery via detoxification and full abstinence (but instead leading to high failure rates and high risk of death of service users), the above-mentioned evidence points at the importance of accepting 'non abstinence-based recovery', i.e. recovery while in long-term OMT and aiming primarily at improving survival, health and quality of life, instead of focusing on substance use and full abstinence. The present lack of consensus limits the uptake and coverage of evidence-based OMT, as too many countries continue to follow outdated, and ineffective, abstinence-based treatment approaches (Wiessing et al., 2023). This gap not only affects the quality and consistency of OMT but also hinders evidence-based policymaking, funding allocations and clinical training. By addressing these issues, our guidance aims to contribute to standardising practices and enhance patient outcomes globally.

Here, we report the results of an international consensus 'Delphi method' study to develop OMT outcomes monitoring guidance (Jünger et al., 2017). The guidance includes an OMT outcomes questionnaire for use in routine clinical practice, developed by professionals and service users from 32 countries (Wiessing et al., 2023). The 'OPTIMUS' guidance (OPioid Treatment outcomes Interview for Maintenance medication USers) aims to support evidence-based opioid disorder treatment, i.e. adequately dosed long-term OMT with high retention and user-centred care, by monitoring treatment outcomes as reported by the service users themselves. It aims to enable and monitor key health and wellbeing outcomes in PWUO and allow for implementation research comparisons across models of care and user profiles.

We have previously reported the background, rationale, study protocol and interim results of the Delphi study (Wiessing et al., 2023). Here, we describe the final results of the Delphi study, in which we aimed to assess the agreement of a large multinational Delphi panel with the proposed set of OMT outcomes, across two survey rounds. We evaluate whether this agreement was similar across the outcome indicators, whether there was improved agreement across both survey rounds, as well as differences by main background variables (e.g. between the service users and professionals). During the process, it became clear that it was necessary for our group to first define and reach consensus on what we meant by OMT. This resulted in the OPTIMUS 'ten key principles of effective OMT' that are included in the guidance (Box 1; online appendix, Annex 1a; Wiessing et al., 2023).

Box 1 The OPTIMUS 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'), 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.
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.
7. The person is regularly assessed using a broad framework around health and quality of life (see the OMT outcomes questionnaire, online appendix, Annex 1b), 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.

Methods

OMT outcomes monitoring guidance, including a draft OMT outcomes questionnaire to follow-up service users and measure user-reported outcomes over the course of their treatment, was prepared by an international group of collaborators, over multiple meetings, between 2018 and 2021 (Wiessing et al., 2023). The draft questionnaire contained an agreed set of OMT outcomes, formatted as questions to the service user, across six treatment outcome domains, plus three end-of-session questions (draft version: online appendix: Annex 3b; final version: online appendix, Annex 1b). A Delphi study method (Jünger et al., 2017) was followed to measure agreement of a Delphi panel, consisting of professionals and service users from the participating countries, with the proposed OMT outcomes and questions in the questionnaire, in two survey rounds. Suggestions from the panel provided as open comments in round 1 were used to adjust the outcomes and outcome questions for confirmation in round 2. The questionnaire is aimed at being directly usable in routine clinical practice in the follow-up of a service user, with a suggested application frequency of every 3 months.

Recruitment of Participating Countries

The initial stages of the work have been described elsewhere (Wiessing et al., 2023). Briefly, a group of collaborators was formed from mostly European countries, based on existing European expert networks. All 29 EUDA (formerly EMCDDA) collaborating countries (the 27 EU member states plus Norway and Türkiye) were invited to participate, of which 19 joined the group (Table 1). Collaborators from additional EU neighbouring and third countries were accepted on an ad hoc basis, e.g. via professional contacts and networks. During the drafting of the outcomes questionnaire, the group increased to around 80 collaborators from 30 countries, of which 27 countries agreed to actively participate in the Delphi study and recruit Delphi panel members. At the end of round 1 of the Delphi study, data from 26 countries had been obtained (Table 1). At the start of round 2, two additional countries agreed to participate in the Delphi study (Austria and Serbia, bringing the number of countries in the Delphi study to $n = 29$, Table 1), and the guidance was drafted, using the comments received from the panel in round 1, by 110 collaborators from 32 countries (online appendix, Annex 1a; Wiessing et al., 2023). Over both Delphi survey rounds, panel members were recruited by collaborators from 28 countries who obtained panel members and data from 29 countries (one panel member lived in a neighbouring country—Table 1).

Design and Data Collection

Panel members were asked to review the quality and relevance of the proposed indicators for assessing outcomes reported by OMT users, in two rounds of Delphi consultation. Panel members rated their agreement with each outcome on a 1-6 Likert scale. In addition, panel members in the first round were asked to provide additional comments in an open-text format on why they felt an outcome was relevant or not and their suggestions for improvement. The outcome (questions) was revised and improved based on the agreement scores and suggestions made by the panel members and the collaborators, and the final consensus of the panel was evaluated in the second round. We thus performed a mixed-methods Delphi study, where the quantitative agreement scores data were used in combination with extensive qualitative data to inform the development of the final outcomes

Table 1 Composition of the Delphi panel by country they are living in, survey round and being an OMT service user

	Round 1		Round 2		Overall total, given repeat participants	
	Total *n*	Of which service users[a]	Total *n*	Of which service users[a]	Total *n*	Of which service users[a]
Albania	21	12	23	14	35	24
Austria	-	-	4	0	4	0
Belgium	7	0	13	1	14	1
Bosnia and Herzegovina	25	14	21	12	35	20
Canada	18	10	10	4	19	11
Cyprus	20	13	46	31	59	42
Czechia	22	11	20	6	31	12
Denmark	12	3	8	1	18	4
Finland	20	10	0	0	20	10
France	19	10	5	0	22	10
Georgia	23	7	16	6	33	9
Germany	19	7	12	2	29	8
Greece	17	9	0	0	17	9
Hungary	20	10	17	7	24	11
Ireland	20	10	8	1	23	10
Israel	0	0	1	0	1	0
Latvia	22	12	19	9	31	17
Lithuania	20	10	20	10	28	13
Netherlands	9	6	17	3	22	7
North Macedonia	20	10	17	3	29	11
Palestine Authority	28	16	57	29	57	30
Poland	20	10	17	7	26	13
Portugal	27	6	23	6	41	12
Serbia	-	-	15	6	13	6
Slovakia	21	11	18	11	32	21
Spain	18	8	25	4	34	8
Switzerland	17	9	11	5	24	14
UK	11	0	17	8	25	8
Ukraine	1	0	13	6	12	6
Total *n*	477	224	473	192	757	347
%		47.0		40.6		45.8

[a]Service users are panel members who answered affirmatively on the question 'I am currently on OMT'. The other panel members are the professionals, who either ticked 'I work directly with people who are on OMT' or 'I work in an area related to OMT'. Austria and Serbia only participated in round 2. The single panel member who reported living in Israel was recruited by the collaborators from the Palestine Authority

questionnaire (Box 2 and online appendix, Annex 1b) (Jünger et al., 2017; Levitt, 2018). We performed a post hoc analysis of the open comments using AI tools to identify overarching themes (online appendix, Annex 3a).

Box 2 The final consensus list of 13 OMT outcomes in 6 domains[a]

Outcome indicators	Core questions
Domain A 'Treatment'	
1. Treatment continuity	1.1 In the last 4 weeks, did you have sufficient prescribed methadone, buprenorphine or other opioid medication, every day that you needed it? (yes/no)
	1.2 If not, were there any days that you had no prescribed opioid medication at all, when you needed it? (yes/no)
	1.3 When you had no medication at all, or it was not sufficient, what were the reasons? (multiple answers possible)
	1.4 In the last 4 weeks, did you only get opioid medication, only psycho-social support, or both? (only medication/ only psycho-social support/ both)
2. Treatment satisfaction	2.1 In the last 4 weeks, how satisfied were you with your whole opioid treatment, including the medications? (score 1—10)
Domain B 'Physical health and risks'	
3. Health	3.1 In general, how would you rate your physical health? (score 1—10)
4. Overdoses	4.1 In the last 3 months, did you have any overdoses? (prefer not to say/ no/ yes)
	4.2 If yes, how many did you have? (number)
5. Injecting drugs	5.1 In the last 3 months, did you inject a drug or substance that was not prescribed for injection? (prefer not to say/ no/ yes)
	5.2 If yes, how often did you do that? (multiple answers possible)
6. Sharing injection materials	6.1 In the last 3 months, did you use injecting materials after they had already been used by others, including a needle or syringe, cup, spoon, filter/cotton, acid/lemon juice or water? (no/ yes/ don't know)
	6.2 In the last 3 months, could you easily obtain sterile needles and syringes or injecting paraphernalia (cup, spoon, filter/cotton, acid/lemon juice or water) when you needed them? (no-yes- don't know)
7. Diseases testing	7.1 In the last 12 months, have you been tested for any infections or diseases? (no/ yes/ don't know)
	7.2 Have you been tested for HIV in the last 12 months, and if yes or no, can you tell me why? (multiple answers possible)
	7.3 Have you been tested for hepatitis C in the last 12 months, and if yes or no, can you tell me why? (multiple answers possible)
	7.4 Have you been tested for any other diseases in the last 12 months, and if yes, which diseases? (no/ yes, namely…)
Domain C 'Mental health'	
8. Mental health	8.1 In general, how would you rate your mental health, including your mood and your ability to think? (score 1—10)
	8.2 In the last 3 months, have you experienced any mental health problems, for example feelings of stress or anxiety, depression or persistent negative thoughts? (no/ yes, namely…)

Outcome indicators	Core questions
Domain D 'Social functioning'	
9. Social support	9.1 How satisfied are you with the support you received from others in the last 4 weeks? This can be emotional support, financial or material support, or any other support. (score 1—10)
	9.2 Have you been homeless any time in the last 12 months, such as living without a steady home, on the streets or temporarily in a hostel or shelter? (no/yes/don't want to say)
10. Social activities	10.1 How satisfied are you with the activities you did with other people in the last 4 weeks? This can be, for example, at home, in the community, with friends or family, at work or in a hobby. (score 1—10)
11. Legal problems	11.1 In the last 3 months, did you have any existing cases or new problems with the police, law or justice? (multiple answers possible)
Domain E 'Substance use'	
12. Substance use	12.1 In the last 4 weeks, did you use any non-prescribed medicines, illicit drugs, alcohol or tobacco? (no/ yes/ prefer not to say)
	12.2 In the last 4 weeks, how often did you use the following substances, and how did you usually take them? (multiple answers possible)
Domain F 'Quality of life'	
13. Quality of life	13.1 In general, how would you rate the quality of your life? This can include all the previous topics we discussed, or other aspects of your life. (score 1—10)
	13.2 In the last 3 months, did your opioid treatment help you improve or maintain the quality of your life? (multiple answers possible)

[a]See the online appendix, Annex 1b, for full details, including the answer categories of the core questions, additional optional questions, start-of-session, baseline and end-of-session questions

Panel Participation

Purposive non-probabilistic sampling was used to recruit panel members who agreed to fill in the Delphi surveys. Collaborators were asked to invite 16 to 20 panel members in their country, i.e. 8 to 10 health professionals with experience in addiction treatment or harm reduction interventions relating to OMT, plus 8 to 10 people who were in OMT ('service users'). To avoid putting pressure on service users to participate in the panel, they were invited by peer workers or by (email or flyers) group announcements where any volunteers could step forward (see for country-specific approaches to service user recruitment the online appendix, Annex 2d). Specific targets were set for the professional backgrounds of the health professionals as well as a 50% panel participation of women among both the health professionals and the service users. Furthermore, it was aimed that service users were currently receiving OMT, at least 18 years old, balanced with regard to time in OMT (with half of them being less than 2 years in OMT and half 2 years or more) (see the Delphi study protocol in the online appendix, Annex 2a).

Surveys

The Delphi surveys included demographic and background questions including: country; age; gender; whether respondents were service users or professionals; their current profession, occupation or professional background; an estimate of how many people the professional treated or supported in a given week (for professionals) and the type of OMT setting they attended as a professional or as a service user. In round 2, panel members were also asked if they had already participated in round 1 or if this was their first participation. The Delphi surveys were run on the EUsurvey platform of the EU Commission.

Translations

Surveys were translated and back-translated to ensure translation accuracy and quality and to allow panel members to respond in their preferred language, which they could choose from a list of available language versions. Non-English language open comments were translated into English using Google Translate and Deepl.com and were subsequently checked for correct translation by the collaborators responsible for each specific country in each respective language.

Data Analysis

The agreement with the proposed outcome domains and indicators by panel members was assessed using the mean of the 1–6 Likert scale scores and the positive proportion of agreement, i.e. the percentage of panel members who scored either '4 — somewhat agree', '5 — agree' or '6 — strongly agree' (Waltz et al., 2010; Polit & Beck, 2006). Statistical measures were provided for each round with the total sample and by sub-groups, differentiating service users and professionals. Unpaired *t* tests were used to test differences between the two sub-groups of panel members and changes between the first and second round. Analyses were performed using the statistical packages STATA versions 17 and 18, SPSS version 27 and Excel 14.5.7.

Feasibility Testing

The OMT outcomes questionnaire was feasibility-tested on 20 patients in four countries (five per country) for duration of the interview and to get qualitative feedback from service users and providers, using a simple protocol (online appendix, Annex 4a).

Ethical Approval

Ethical approval of the Delphi study protocol was obtained from the Ethical Board of the Czech National Monitoring Centre for Drugs and Addictions, Prague, Czechia, and separately in four of the participating countries on request of the collaborators (Spain, Switzerland, Cyprus and Canada) (see the Delphi study protocol in the online appendix,

Table 2 Composition of the Delphi panel by being an OMT service user or professional, survey round, gender, age and inpatient setting

	Round 1	*p* value difference Service users/professionals	Round 2	*p* value difference Service users/professionals	Overall	*p* value difference Service users/professionals	*p* value difference rounds 1&2[c]
Service users[a]							
n	224		192		347		
% women[d]	26.3		22.6		24.3		0.37
% ≤ age 45	58.0		60.5		61.3		0.61
% inpatient setting[b]	7.1		8.9		7.8		0.50
Professionals							
n	253		281		410		
% women[d]	53.6		52.7		53.8		0.84
% ≤ age 45	42.7		51.8		48.4		0.04*
% inpatient setting[b]	3.2		12.5		7.1		0.00**
All panel members							
n	477		473		757		
% women[d]	40.7	0.00*	40.5	0.00*	40.2	0.00*	0.95
% ≤ age 45	49.9	0.00*	55.3	0.06	54.3	0.00*	0.10
% inpatient setting[b]	5.0	0.05	11.0	0.22	7.4	0.71	0.00**
% service user[a,e]	47.0	0.19	40.6	0.00*	45.8	0.02*	0.05

*$p < 0.05$; **$p < 0.01$. [a]Service users are panel members who answered affirmatively on the question 'I am currently on OMT'. Professionals are the other panel members, who either ticked 'I work directly with people who are on OMT' or 'I work in an area related to OMT'. [b]Percentage inpatient setting is shown across professionals and service users combined (i.e. being treated or working exclusively in an inpatient setting). [c]*p*-value for difference in proportions (*z* test). [d]A small minority identified as non-binary (1% in round 1 and 0.4% in round 2) or preferred not to state their gender (0.8% and 0.4% respectively). [e]This row reports the *p*-value associated with the null hypothesis that the percentage of service users is equal to 50.0%, that is, the sample is equally representative of service users and professionals

Annex 2a, p8). Separate approval by the Ethical Board in Czechia was obtained for the protocol for feasibility testing of the questionnaire.

Results

Delphi Panel

A total of 757 panel members from 29 countries participated across both survey rounds (Table 1). Of the panel members, 347 (46%) self-identified as OMT service users and 410 (54%) as OMT professionals. Overall, 58% were men and 40% women; however, the proportion of women was much larger among professionals than among service users (54% vs. 24%, Table 2). A small minority identified as non-binary ($n = 6$ or 0.8%) or did not state their gender ($n = 10$ or 1.3%). The proportion aged ≤ 45 was larger among service users than among professionals (61% vs. 48%). The professionals were asked to report their professional background in 14 different categories (including 'other') of which 'Addiction doctor', 'General practitioner', 'Nurse', 'Psychiatrist', 'Psychologist', 'Social (care) worker' and 'other' were the most frequently mentioned (Table S1). Overall, the panel used 22 language versions of the surveys (21 in each round).

Between the two rounds, no statistically significant differences were found by gender or being service user/professional. However, among the professionals, the proportion who reported working exclusively in an inpatient setting changed from 3.2% in round 1 to 12.5% in round 2, while the proportion aged ≤ 45 increased from 42.7 to 51.8% (both $p < 0.01$). Of the 473 panel members in round 2, 180 (38.1%) stated they had also participated in round 1 (online appendix, Table S4).

Panel Agreement Scores for the Proposed OMT Outcomes

In both Delphi survey rounds, high agreement scores were obtained for (the core questions of) all proposed outcomes (round 1: overall mean score 5.06 out of 6, 95%CI 4.99–5.12, range in mean scores 4.90–5.26; round 2: overall mean 5.19, 95%CI 5.12–5.25, range 4.99–5.36) (Tables 3 and 4).

An overall increase in agreement scores was observed between rounds 1 and 2 of on average 0.13 points (from 5.06 to 5.19; 95%CI 0.04–0.21) with statistically significant changes in 8 of the 13 outcomes. A separate single question asking the panel members for their agreement with the list of outcomes (core questions) as a whole resulted in a larger increase of 0.25 points (from 4.95 to 5.19; 95%CI 0.15–0.35) (Table 5).

Slight differences were observed between the overall mean scores in answers provided by service users and professionals, with the professionals giving the highest scores in both rounds but in particular in round 2 (service users/professionals: round 1 5.04/5.08 ($p < 0.01$); round 2: 5.08 /5.25 ($p < 0.01$)).

In both rounds, the outcomes in domains A ('Treatment'), B ('Physical health') and E ('Substance use') received higher agreement scores than the outcomes in domains C ('Mental health'), D ('Social functioning') and F ('Quality of life'). However, this difference diminished, from 0.17 points in round 1, to 0.06 points in round 2 (Tables 3 and 4).

Table 3 Delphi panel agreement scores for the core questions of the 13 outcomes in round 1; on a 1–6 Likert scale with 6 = maximum

Outcome (Domain)[a]	Service users ($n = 224$)		Professionals ($n = 253$)		Difference in means	The whole group ($n = 477$)	
	Mean (95% CI)	Positive agreement %	Mean (95% CI)	Positive agreement %		Mean (95% CI)	Positive agreement %
1 Treatment continuity (A)	5.12 (4.98–5.26)	94.2	5.04 (4.91–5.17)	92.9	0.08	5.08 (4.98–5.17)	93.5
2 Treatment satisfaction (A)	5.27 (5.16–5.39)	96.9	5.05 (4.93–5.17)	92.9	0.22*	5.16 (5.07–5.24)	94.7
3 Physical health (B)	5.12 (4.99–5.24)	94.6	4.93 (4.81–5.05)	93.3	0.19*	5.02 (4.93–5.10)	93.9
4 Overdose (B)	5.00 (4.84–5.15)	89.3	5.02 (4.89–5.14)	92.5	0.02	5.01 (4.91–5.11)	91.0
5 Injecting drugs (B)	4.97 (4.81–5.14)	89.3	5.32 (5.20–5.43)	96.4	0.35**	5.16 (5.06–5.25)	93.1
6 Sharing injection materials (B)	5.01 (4.85–5.18)	89.3	5.24 (5.13–5.35)	96.0	0.23	5.13 (5.04–5.23)	92.9
7 Diseases screening (B)	5.32 (5.21–5.43)	96.9	5.22 (5.09–5.34)	94.5	0.10	5.26 (5.18–5.35)	95.6
8 Mental health (C)	5.00 (4.86–5.13)	92.4	4.91 (4.79–5.03)	93.7	0.09	4.95 (4.86–5.04)	93.1
9 Social support (D)	4.86 (4.72–5.00)	89.7	5.00 (4.88–5.12)	93.3	0.14	4.93 (4.84–5.02)	91.6
10 Social activities (D)	4.88 (4.73–5.02)	88.8	5.10 (4.99–5.21)	94.9	0.22	4.99 (4.90–5.08)	92.0
11 Legal problems (D)	4.78 (4.61–4.94)	86.2	5.01 (4.89–5.14)	92.9	0.23	4.90 (4.80–5.00)	89.7
12 Substance use (E)	5.15 (5.01–5.30)	92.4	5.20 (5.08–5.32)	95.7	0.05*	5.18 (5.09–5.27)	94.1
13 Quality of life (F)	5.00 (4.86–5.14)	90.6	4.97 (4.85–5.09)	93.3	0.03*	4.99 (4.89–5.08)	92.0
Total	5.04	91.6	5.08	94.0	0.04	5.06	92.9
(95% CI)	(4.94–5.13)	(89.6–93.6)	(5.00–5.16)	(93.2–94.8)		(4.99–5.12)	(91.9–93.8)

A Domain A 'Treatment', *B* Domain B 'Physical health', *C* Domain C 'Mental health', *D* Domain D 'Social functioning', *E* Domain E 'Substance use', *F* Domain F 'Quality of life'. *$p < 0.05$; **$p < 0.01$ in t-tests for independent samples. [a]Additional optional questions for each outcome were introduced in round 2 (based on open comments received in round 1) so that the outcome questions of round 1 became 'core questions' in round 2. A second outcome existed in domain C (mental health) during round 1 but was merged with the outcomes shown here due to both outcomes overlapping too much. Therefore outcome labelling as shown here is consistent with that in round 2 and is directly comparable with Table 4 (i.e. the outcomes 9–13 shown here were originally numbered 10–14 in round 1). Question format was as follows (with text in square brackets varying per outcome or domain): 'To what extent do you agree this indicator is helpful to assess the [continuity of the drug treatment] experienced by the client?' See full details of the core and optional questions in the online appendix, Annex 1b

Table 4 Delphi panel agreement scores for the core questions of the 13 outcomes in round 2; on a 1–6 Likert scale with 6 = maximum

Outcome (domain)[a]	Service users ($n = 192$)		Professionals ($n = 281$)		Difference between means	The whole group ($n = 473$)	
	Mean (95% CI)	Positive agreement %	Mean (95% CI)	Positive agreement %		Mean (95% CI)	Positive agreement %
1 Treatment continuity (A)	5.16 (5.07–5.26)	99.0	5.31 (5.23–5.39)	97.9	0.15*	5.25 (5.19–5.31)	98.3
2 Treatment satisfaction (A)	5.14 (5.03–5.25)	97.9	5.21 (5.12–5.29)	97.5	0.07	5.18 (5.11–5.25)	97.7
3 Physical health (B)	4.94 (4.82–5.05)	96.9	5.02 (4.92–5.13)	94.7	0.08	4.99 (4.91–5.07)	95.6
4 Overdose (B)	4.99 (4.85–5.13)	92.2	5.26 (5.16–5.36)	96.1	0.27**	5.15 (5.07–5.23)	94.5
5 Injecting drugs (B)	4.98 (4.86–5.10)	94.8	5.29 (5.20–5.37)	97.5	0.31**	5.16 (5.09–5.23)	96.4
6 Sharing injection materials (B)	5.10 (4.98–5.21)	97.4	5.37 (5.29–5.45)	98.2	0.27**	5.26 (5.19–5.33)	97.9
7 Diseases screening (B)	5.23 (5.13–5.34)	99.0	5.44 (5.36–5.52)	98.6	0.21**	5.36 (5.29–5.42)	98.7
8 Mental health (C)	5.15 (5.06–5.24)	99.0	5.23 (5.14–5.31)	98.6	0.08	5.20 (5.13–5.26)	98.7
9 Social support (D)	5.04 (4.92–5.16)	96.4	5.12 (5.02–5.22)	96.1	0.08	5.09 (5.01–5.16)	96.2
10 Social activities (D)	4.94 (4.83–5.06)	94.8	5.11 (5.02–5.20)	96.8	0.17*	5.04 (4.97–5.11)	96.0
11 Legal problems (D)	5.07 (4.94–5.19)	95.3	5.31 (5.22–5.40)	98.2	0.24**	5.21 (5.14–5.28)	97.0
12 Substance use (E)	5.18 (5.08–5.29)	97.9	5.39 (5.31–5.48)	98.9	0.21**	5.31 (5.24–5.37)	98.5
13 Quality of life (F)	5.17 (5.09–5.26)	99.0	5.23 (5.14–5.31)	97.9	0.06	5.21 (5.14–5.27)	98.3
Total	5.08	96.9	5.25	97.5	0.17**	5.19	97.2
(95% CI)	(5.02–5.14)	(95.6–98.2)	(5.18–5.32)	(96.7–98.2)		(5.12–5.25)	(96.4–98.0)

See full details of the core and optional questions in the online appendix, Annex 1b. *A* Domain A 'Treatment', *B* Domain B 'Physical health', *C* Domain C 'Mental health', *D* Domain D 'Social functioning', *E* Domain E 'Substance use', *F* Domain F 'Quality of life'. *$p < 0.05$; **$p < 0.01$ in t-tests for independent samples. [a]Additional optional questions for each outcome were introduced in round 2 (based on open comments received in round 1) so that the outcome questions of round 1 became 'core questions' in round 2. A second outcome existed in domain C (Mental health) during round 1 but was merged with the outcomes shown here due to both outcomes overlapping too much. Therefore outcome labelling as shown here is consistent with that in round 2 and is directly comparable with Table 4 (i.e. the outcomes 9–13 shown here were originally numbered 10–14 in round 1). Question format was as follows (with text in square brackets varying per outcome or domain): 'To what extent do you agree this indicator is helpful to assess the [continuity of the drug treatment] experienced by the client?'

Table 5 Changes in Delphi panel agreement scores for the core questions of the 13 outcomes between rounds 1 and 2; on a 1–6 Likert scale

Outcome (Domain)	Round 1 ($n=477$) Mean (95% CI)	Round 2 ($n=473$) Mean (95% CI)	Change	(95% CI)[a]
1 Treatment continuity (A)	5.08 (4.98–5.17)	5.25 (5.19–5.31)	0.17**	(0.06; 0.28)
2 Treatment satisfaction (A)	5.16 (5.07–5.24)	5.18 (5.11–5.25)	0.02	(−0.08; 0.13)
3 Physical health (B)	5.02 (4.93–5.10)	4.99 (4.91–5.07)	−0.03	(−0.14; 0.09)
4 Overdose (B)	5.01 (4.91–5.11)	5.15 (5.07–5.23)	0.14*	(0.01; 0.27)
5 Injecting drugs (B)	5.16 (5.06–5.25)	5.16 (5.09–5.23)	0.00	(−0.11; 0.13)
6 Sharing injection materials (B)	5.13 (5.04–5.23)	5.26 (5.19–5.33)	0.13*	(0.01; 0.24)
7 Diseases screening (B)	5.26 (5.18–5.35)	5.36 (5.29–5.42)	0.10	(−0.01; 0.20)
8 Mental health (C)	4.95 (4.86–5.04)	5.20 (5.13–5.26)	0.25**	(0.14; 0.35)
9 Social support (D)	4.93 (4.84–5.02)	5.09 (5.01–5.16)	0.16**	(0.04; 0.28)
10 Social activities (D)	4.99 (4.90–5.08)	5.04 (4.97–5.11)	0.05	(−0.07; 0.16)
11 Legal problems (D)	4.90 (4.80–5.00)	5.21 (5.14–5.28)	0.31**	(0.18; 0.44)
12 Substance use (E)	5.18 (5.09–5.27)	5.31 (5.24–5.37)	0.13*	(0.02; 0.24)
13 Quality of life (F)	4.99 (4.89–5.08)	5.21 (5.14–5.27)	0.22**	(0.11; 0.33)
Mean agreement score of the individual outcomes	5.06 (4.99–5.13)	5.19 (5.12–5.25)	0.13**	(0.04; 0.21)
Agreement score for the list of outcomes as a whole	4.95 (4.87–5.03)	5.19 (5.13–5.26)	0.25**	(0.15; 0.35)

A: Domain A 'Treatment', *B*: Domain B 'Physical health', *C*: Domain C 'Mental health', *D*: Domain D 'Social functioning', *E*: Domain E 'Substance use', *F*: Domain F 'Quality of life'. *$p<0.05$; **$p<0.01$ in t-tests for independent samples. [a]Due to the possibility of negative values, the hyphen in this column is replaced by a semicolon '; '

Panel Agreement Scores for Adding Optional Questions to the OMT Outcomes

The inclusion, in round 2, of additional optional questions for the outcomes, as suggested by the open comments received in round 1, was strongly supported in round 2, with an overall mean agreement score for the optional questions of 5.17 out of 6 (95%CI 5.14–5.20) (Table S2), which was almost identical to the mean score of 5.19 (95%CI 5.12–5.25) for the core questions in round 2 (Table 5).

Panel Agreement Scores for Adding Start-of-Session, Baseline and End-of-Session Questions

There was strong agreement in round 2 for inclusion of three short sections with additional questions to the outcomes questionnaire (agreement scores: start-of-session 5.21 (95%CI 5.13–5.30), baseline 5.06 (95%CI 4.96–5.15) and end-of-session 5.24 (95%CI 5.17–5.32) (Table S3).

For the final list of core questions corresponding to the selected outcome indicators, see Box 2 (see online appendix, Annex 1b for the full questionnaire).

Open Comments

The possibility to provide qualitative full-text comments to each of the proposed outcomes in both Delphi surveys resulted to be a crucial part of the panel members' feedback. In round 1, 1468 open comments were received (on average 3.1 per respondent) while 902 open comments (1.9 per respondent) were received in round 2 (Table S4). One service user in the Delphi panel commented 'I have the feeling that you have taken the feedback from last year [round 1] into account. In any case, I find many answers/comments from myself in the optional questions that you offer this year [round 2]. I really enjoy this experience. Thank you.' All open comments are available in the online appendix, Annex 3a. Artificial intelligence analysis of the open comments suggested that a wide range of themes emerged in the comments and that these themes or categories varied across domains and indicators (online appendix, Annex 3a).

Feasibility Testing

In the limited feasibility testing performed, the interview duration of the outcomes questionnaire strongly depended on the inclusion, or not, of optional questions (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, service users found the interview a bit too long; in other cases, the clinician said a longer interview was actually helpful, allowing for more discussion about interventions. Qualitative feedback was overall positive from both service users and providers. Some service users providing positive feedback indicated that 'some questions have never been asked to them throughout their full OMT care.'

Discussion

To the best of our knowledge, we present the first large international consensus study for identifying outcomes to be monitored during the delivery of an evidence-based highly effective long-term maintenance treatment (OMT) for opioid use disorder. We achieved a high and increasing consensus throughout the two rounds of our Delphi study on what outcomes and domains to use to evaluate treatment success in service users, relying on service user–reported outcomes rather than urine testing or service provider reports. People with lived experience in OMT were involved in the process from the outset, as part of our collaborative group that designed and drafted the guidance and outcomes questionnaire, ensuring both service user–centred and service user co-designed outcomes (Trujols et al., 2013). We explicitly include outcomes across the three WHO dimensions of health (physical, mental and social) as well as the domains of the treatment itself, substance use and quality of life. We succeeded in recruiting a large international Delphi panel from 29 countries, consisting of almost as many service users as professionals, and almost as many women as men, thus incorporating evidence based on lived experience from a relatively wide range of social and cultural realities in (western) high- and upper-middle income countries. While OMT already is the intervention with the strongest evidence-base in the scientific literature for saving and improving the lives and protecting the health of people who use opioids (EUDA, 2024), our work aims to promote international consensus on

monitoring the outcomes of OMT, through the use of service user–reported outcomes in six key domains that cover the major public health outcomes associated with opioid use disorder.

Our choice of focusing on OMT service user–reported outcomes is in full agreement with previous reviews (Trujols et al., 2013, 2015; Marchand et al., 2019) but also research in other fields of chronic conditions (i.e. people with diabetes, liver disease, cardiovascular disease) whose progression and response to therapy strongly depend on attitudes, perceptions and behaviours of the user/patient, i.e. patient or service user–reported outcomes (Lagisetty et al., 2017; Lintzeris et al., 2021; Nielsen et al., 2016; Roux et al., 2016; Sanger et al., 2022). Neglecting the needs and adjustments expressed by service users during their treatment experience may not only affect the quality of the service user-provider relationship but also treatment retention and long-term outcomes (Davis et al., 2020). Urine testing has not been shown to be associated with better outcomes during OMT (McEachern et al., 2019). Building a tool to monitor service user-reported outcomes for long-term treatment underlines the importance of providing person-centred care to reach the full range of relevant and sustainable individual and public health outcomes, some of which have so far scarcely been covered in opioid use disorder treatment outcome studies (Marchand et al., 2019; Trujols et al., 2015; Wiessing et al., 2018).

Our Delphi study provided strong support for the proposed OPTIMUS OMT outcomes questionnaire, with a final mean agreement score of 5.19 on a 1–6 Likert scale (where 5 was 'agree' and 6 'strongly agree') for the core questions across all 13 outcomes. Our consensus study suggests that some outcomes that may be highly relevant to the individual and to service providers, such as mental or physical health, quality of life, social support and social activities, but are often neglected in favour of substance use outcomes (e.g. abstinence), need to be equally recognised as major outcomes of OMT. This is, not using opioid agonist medication for medication-assisted treatment with short-term goals, but as a maintenance therapy (OMT) in a comprehensive care approach within a long-term perspective. This is in line with previous research showing that treatment improves quality of life (Carlsen et al., 2019), including physical and mental health, and that having social relationships and social support is associated with retention in treatment (Marks et al., 2020; Pasman et al., 2022; Tierney et al., 2023; Zhou et al., 2017; Zhou & Zhuang, 2014).

Other studies have proposed indicators to evaluate outcomes of drug treatment (Karnik et al., 2022; Marsden et al., 2008; Stirling et al., 2023; World Health Organization, 2020). However, these have been developed for specific national contexts and are not based on an international consensus process including people with lived OMT experience. Also, most of these studies are not focused on people who use opioids (Marsden et al., 2008; Stirling et al., 2023; World Health Organization, 2020), in some cases resulting in relatively generic and unspecific indicators for this key group of service users. Some studies combined patient-level and system-level indicators, or indicators that require additional complex methodology (e.g. mortality studies), making them difficult to apply in clinical practice (Karnik et al., 2022; Stirling et al., 2023). Although we here present a service user–centred set of questions for monitoring OMT outcomes in a wide range of settings (e.g. both low-threshold and inpatient), 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 (Lambdin et al., 2015; Schackman, 2010; Silverman, 2009; Wiessing et al., 2017).

Our outcomes questionnaire and guidance for assessing patient outcomes is in no way intended to replace existing clinical guidance on OMT provision (WHO 2009), but rather

to complement it with a set of consensus service user–reported and co-designed outcomes for OMT outcomes monitoring. Importantly, our outcomes questionnaire is designed for the service provider taking direct action together with the service user, i.e. the core screening questions are meant to trigger more (optional) questions in case problems are detected in a specific outcome domain and then to lead to the appropriate interventions and referrals, whereas our end-of-session questions aim to commit the service provider to an explicit intervention and date of next visit of the service user. Our questionnaire can be used for: (a) assessing the situation of clients at the time when they present into treatment, including their broader problems and needs; (b) assessing clients' progress over time by comparing their current assessment to the previous ones; (c) assessing clients' situation at the time they are completing treatment, in comparison to previous and initial assessments; (d) assessing client's outcomes across services and client types; (e) aggregating service-level outcomes across multiple providers to be compared across jurisdictions ('benchmarking' (NADA, 2024)). Thus, our set of outcome indicators has also the potential to be used as a tool for exploring specific research questions, for instance concerning the link between a specific model of care and user outcomes or identifying which profile of users may better respond to OMT in terms of user-reported outcomes.

An important limitation of our work is that our outcomes questionnaire/guidance has not yet been extensively tested in clinical practice. Our questionnaire has so far been feasibility-tested only on a small number of service users ($n = 20$, see online appendix, Annex 4). However, these first feasibility testing results are encouraging, with positive feedback from both clinicians and service users. In some cases, service users found the interview a bit too long; in other cases, the clinician said a longer interview was actually helpful, allowing for more discussion about interventions (Sharma, 2022). If an interview would be becoming too long, it might be interrupted and continued in the next visit; however, the feasibility of this approach has not been tested. The results from our limited feasibility testing suggest that the time investment (around 15 min without, 30 min with, optional questions) is feasible in clinical practice, especially if only repeated every 3 months as recommended (or, for some service users, perhaps less frequently). We have had some signals (a few individuals in two countries) that some professionals who were critical of our questionnaire refused to participate in the Delphi panel, which could have resulted in upward bias in the agreement scores. Service users were in some countries helped by a professional to fill in the surveys; this may have introduced bias as answers may not have always been blinded to the service provider as was requested in the study protocol and/or, in some of those cases, the service provider may have (partially) suggested the answers. For more detail regarding recruitment of service users per country, see online appendix, Annex 2d. Our consensus study is, however, based on a solid methodology and fills a gap in the information needed by providers to capture service user perspectives and improve their treatment practices as well as to cover key health outcomes that determine survival, health and quality of life (Jünger et al., 2017; Levitt, 2018; Vogel et al., 2019; Wiessing et al., 2018).

Our guidance aims to contribute to reducing the present lack of consensus in terms of both monitoring OMT treatment outcomes, wider drug policies and even key drug treatment terminology, which altogether hampers uptake and coverage of OMT globally and may be a key factor driving high opioid-related mortality in some regions (Wiessing et al., 2023). Indeed, a catastrophic rate of opioid overdose mortality in some countries needs urgently to be reversed. This is likely only possible by setting high-ambition goals for OMT coverage nationally and internationally (Wiessing et al., 2023). In Europe, several countries currently report over 90% OMT coverage of their estimated population of people who use opioids, a level that is not seen elsewhere (EMCDDA 2024). At the same

time, synthetic opioids such as fentanyls have still hardly gained ground in Europe, and where they did this is only in countries with very low OMT coverage, suggesting that high levels of OMT coverage may to a great extent replace the market for and need for synthetic opioids. Restricting legal prescriptions of opioid medications, as was done in the US but not in the EU, likely has the opposite effect to the one intended, only resulting in an increase in the availability and market penetration of illicit opioids, as the demand for opioids remains unchanged (Hammersley et al., 1995). The severe restriction of legal prescriptions in the US, in combination with low OMT coverage, may be among the key drivers fanning the current mortality epidemic related to synthetic opioids. Similarly to opioids, in Scotland, the implementation of a strong restriction policy on the prescription of benzodiazepines, with the intention to reduce deaths and morbidity associated with benzodiazepines, resulted in the opposite effect, with illicit and fake benzodiazepines entering the market and increasing mortality (McAuley et al., 2022). Setting a high and ambitious goal for the coverage of low-threshold and continuous OMT with legal prescription opioids will likely contribute to reducing the demand for illicit opioids and prevent opioid-related crime and illicit trade, as well as saving the lives of, and reducing morbidity in, people who use drugs.

By focusing on service user-reported and public health-centred outcomes, our OPTIMUS OMT outcomes monitoring guidance aims to contribute to improving user-provider communication, access to and retention in care, and thus to the survival, health and quality of life of OMT service users.

Supplementary Information The online version contains supplementary material available in an online appendix at https://doi.org/10.1007/s11469-024-01426-6.

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Data Availability All data from the Delphi study are available in the online appendix, Annex 3a.

Declarations

Conflict of Interest The authors declare no competing interests.

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