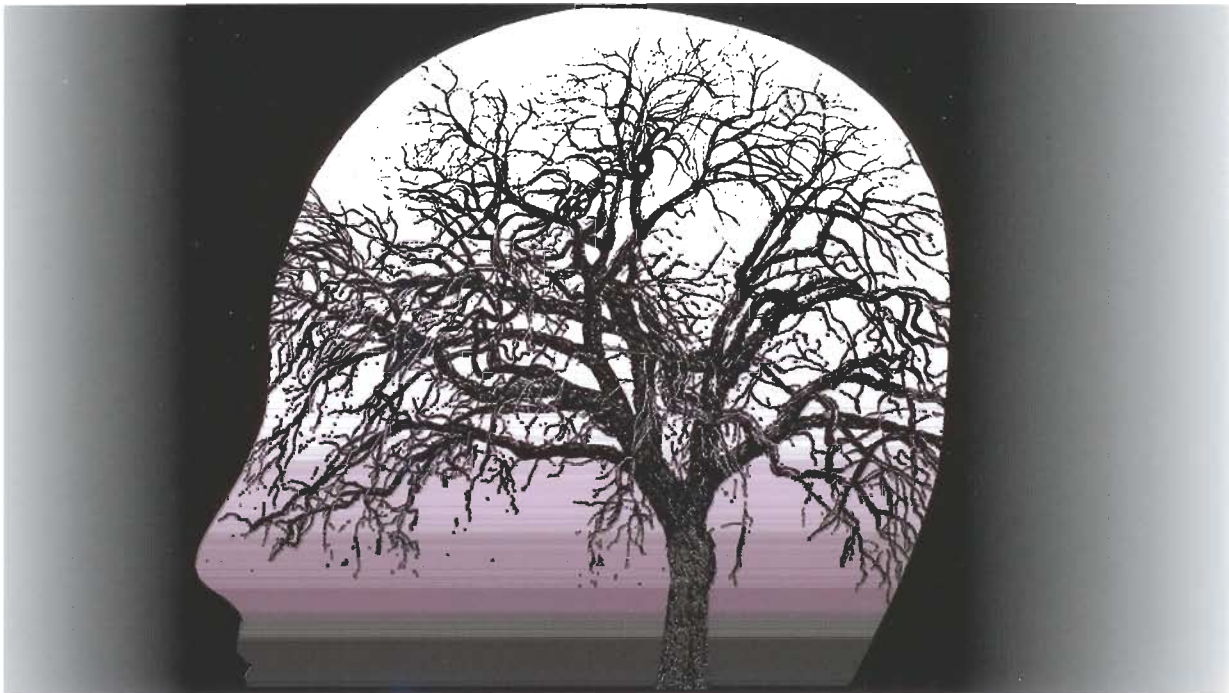


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Opiate Dosage Adequacy Scale (O.D.A.S.): A clinical diagnostic tool as a guide to dosing decisions

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Methadone dosage is one of the main modulating factors involved in treatment effectiveness. Programmes where higher mean doses are prescribed are achieving better results in terms of patient retention, decrease in heroin consumption and reduction of addiction severity scores ⁽¹⁾. On an individual level, however, the distinction between high and low doses is purely arbitrary, since response to a particular methadone dose can vary enormously from one patient to another. As with any other drug, variability depends both on pharmacokinetic factors (that mediate the relationships between doses and plasma levels) and pharmacodynamic factors (that mediate the relationships between plasma levels and effects). As a result, each patient should be provided with the most appropriate dose to ensure the optimum therapeutic effects.

An appropriate dose is usually considered as the dose that: a) suppresses the signs and symptoms of opioid withdrawal, b) reduces opioid-drug craving, and c) reduces the reward effects of illicit opioids ("blockade") ^(5,6). Assessing and adjusting methadone dosage for each individual patient should fundamentally remain a clinical process. The determination of serum methadone levels (SML) may, however, be useful in some cases.

In the clinical setting, an experienced physician will assess dosage heuristically. In the research field, several different scales have been used to examine items such as withdrawal ⁽⁴⁾, craving ⁽²⁾ and checklists with reported symptoms ⁽³⁾. Each of these scales, however, measures only one of the items that should be borne in mind when adjusting methadone dosage to optimum levels. For example, if doses are considered to be adequate when they cover withdrawal symptoms only, that will lead to an understimulation of the dose required.

For this reason we have devised the *Opiate Dosage Adequacy Scale* (ODAS). This is intended to provide a means to achieve a theoretical construct named "adequacy of dosage". ODAS attempts to provide a clinical measurement of the degree to which a given methadone dose is "adequate" for an individual patient. In practical terms, a

methadone dose is considered as “adequate” when:

1. It suppresses the opiate withdrawal syndrome.
2. It significantly reduces opioid-drug craving in the subject’s most common drug-use situations or cues.
3. In the event of heroin consumption, the patient experiences none of the drug’s significant effects (“blockade effect” or cross-tolerance).
4. It produces no significant symptoms of overmedication.
5. It is associated with the reduction of continuing illicit opiate (i.e. heroin) consumption.
6. The patient perceives that the methadone dose “covers” his/her withdrawal symptoms over the 24 hour inter-dose period.

ODAS is a semi-structured clinical interview containing 10 items that address the six attributes named above. The answers to each of the questions are coded by Likert-type scores from 0 to 5. ODAS scores may be interpreted both quantitatively and qualitatively. First, they provide a total score from the weighted sum of individual item scores. The higher the total score, the greater the degree of “adequacy”. Secondly, at a certain cut-off point, each patient’s dose can be categorized as “adequate” or “inadequate”.

In our clinical experience with this scale, we have seen that, during the first few weeks of treatment, “adequate” scores rose steadily, in line with increases in methadone dosage, up to a value considered to be a maintenance dose. We have also seen, however, that a high percentage of these patients have total scores categorized as “inadequate” dosage. The reliability and validity of ODAS is currently under examination in two separate studies with samples from patients under treatment with either methadone or buprenorphine.

ODAS would enable the following hypotheses to be tested in a research setting:

1. Patients taking very different methadone doses may achieve similar scores on the “adequacy” scale (i.e. for some subjects, a dose of 100 mg/day would be “adequate”, whereas other patients only achieve “adequacy” at doses of 140 mg/day).
2. It is likely that higher total scores on the “adequacy” scale will be found among patients taking high doses of methadone.
3. If a wide-ranging sample of patients with “adequate doses” were selected, we would find a tighter-fitting correlation with SML. As in standardized weight and height tables, a range of variability for SML could be determined for each “adequate dose”.
4. The total ODAS score, used as an independent variable, would have a higher predictive power over the outcomes of methadone maintenance programmes (i.e. retention rate and heroin consumption) than the simple value of the methadone dose itself.

We hold a positive clinical view of this instrument and hope that the validation studies will confirm our hypothesis. If that is the case, then ODAS could become a useful clinical tool able to help physicians make informed dosage-related decisions.

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OPIATE DOSAGE ADEQUACY SCALE

(O.D.A.S.)

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- Date of the interview: __ / __ / __
- First name and family names of the patient: _____
- Methadone dose during the last seven days: _____ mgrs/day.
- Length of time on the current methadone programme: __ weeks.
- Frequency of use of other substances during the last seven days: (state the number of days when any of the following were consumed)
Cocaine: __; Alcohol: __; Cannabis: __; Benzodiazepines: __; Amphetamines: __
; Other (specify): _____

GENERAL INSTRUCTIONS

The ODAS is a brief semi-structured clinical interview whose purpose is to assess clinically how appropriate the dose of methadone prescribed in the context of the patient's methadone maintenance program is for his or her individual needs. This instrument innovates by offering a more systematic and informed approach to the measurement of the construct referred to as the "adequacy" or the correctness of the methadone dose. Operationally, we interpret a methadone dose as being "adequate" when the patient: a) uses no heroin or uses it only occasionally; b) does not experience continuous opiate withdrawal symptoms (OWS) – if there are any, they are very mild; c) does not experience frequent episodes of craving for heroin – any craving present is very mild, d) in the event of heroin use, the patient does not experience its subjective effect – any effects are very mild (narcotic blockade or crossed tolerance); and e) does not experience continuous symptoms of overmedication – if any are felt, they are very mild.

The ODAS is designed to assess the degree of adequacy of the dose taken by the patient during the previous seven days or so. As a minimum, therefore, the patient has to continue on that same dose during this period. This will ensure that the patient has reached the steady state corresponding to that dose.

The ODAS clinical interview comprises 10 items that evaluate the six specific attributes or components of the construct "dose adequacy": *Continuous use of heroin* (item 1); *Narcotic blockade or crossed tolerance* (item 2); *Objective OWS* (items 3a and 3b); *Subjective OWS* (items 4a and 4b); *Craving for heroin* (items 5a and 5b); and *Overmedication* (items 6a and 6b).

All the questions of the ODAS have the same structure. First the particular construct component that the question aims to evaluate is stated (in bold and italics). Then follows the main question in the item (in italics). However, given that this is a semi-structured clinical interview, it is not strictly necessary to formulate this question as literally presented here. The interviewer can paraphrase it to an extent considered appropriate at that time and in that context. The objective is for the patient to understand correctly the essence of the question being asked. To assist in ensuring this understanding, the main question is followed by one or more supplementary questions (shown in italics and preceded by a dash).

The expected usefulness of ODAS is not only clinical, in helping to optimize the methadone dose for each individual recipient, but extends to applications in the field of research. This instrument is only intended to provide an evaluation of the degree of adjustment of the dose. The decision on the need to modify the methadone dose, as a function of the assessment provided by the ODAS, is a clinical decision that will depend on many other factors, some of which may be raised and evaluated in the interview by utilizing the five Additional Items in the questionnaire. These items do not form part of the ODAS proper, so they have not been included in the quantitative scoring.

This is a preliminary version. The ODAS is currently in process of validation, as a result of which a few minimal changes may be made before the definitive version is ready. The procedure for obtaining the total scores from this interview will be reported

when this study is complete.

1. Continuous consumption of heroin

During the last seven days, how frequently have you used heroin?

- *Have you used heroin on any occasion during the last seven days?*
- *If you have, on how many of the last seven days?*
- *If you have been using heroin every day (or most days), how many times a day, on average, have you been using it?*
 - On none of the last seven days5.
 - On one, two or three of the last seven days.....4.
 - On four, five or six days of the last seven days.....3.
 - Once or twice every day.....2.
 - Three or more times every day.....1.

>>> CUT-OFF POINT: If a patient has not used heroin at any time during the last week (score 5 in questions 1 and 2), he or she should pass directly to question 3.

2. Narcotic blockade or crossed tolerance

How intense was the effect you felt from the dose or doses of heroin that you used during the last seven days?

- *Your methadone dose during the last seven days was X milligrams per day. Have you felt the effect of the dose or doses of heroin that you used during the last seven days?*
- *How intense was its effect?*
- *Was the effect different from what you felt when you were not being treated with methadone?*
- *Was the effect different from when you were taking a bigger or smaller dose of methadone?*

Show the patient CARD 1.

Score: ___/ (The score for this item is obtained by inverting the figure selected by the patient on the analogue-visual scale of Card 1: e.g. when a value of 1 is selected on the Card, this is equivalent to a score of 5 for this item, and so on, for each of the other items).

3a. Frequency of an objective OWS (Opiate Withdrawal Syndrome).

Some people taking doses of methadone experience withdrawal symptoms such as: cramps and muscular pains, feeling your hair standing on end, a runny nose, wanting to cry, yawning, stomach cramps or diarrhea, palpitations, sweating, and generally feeling bad. These are symptoms that other people you are with can generally see.

During the last seven days, how frequently have you felt any of these symptoms?

- *During the last seven days, have you felt withdrawal symptoms at*

any time?

- Have you had any symptoms such as and? (at this point repeat to the patient the symptoms listed in the main question).
- If you have, on how many of the last seven days did you have these symptoms?

(To determine the presence of an objective OWS clinically, the patient must present two or more of the symptoms listed in the main question, unless the interviewer identifies some other clinical condition of the patient that provides clearer confirmation of an objective OWS.)

- On none of the last seven days.....5.
- On one or two of the last seven days.....4.
- On three to six of the last seven days.....3.
- On each of the last seven days, once or twice a day.....2.
- On each of the last seven days, more than twice a day or very often.....1.

>>> CUT-OFF POINT: If a patient has not presented at least two of these symptoms at any time during the last week (score 5 in questions 3a and 3b), pass directly to question 4a.

3b. Intensity of an objective OWS

During the last seven days, how intense, on average, were the withdrawal symptoms you say you felt?

- On the occasions when you felt these symptoms, how intense were they, on average?

Show the patient CARD 2.

Score: ___/ (The score for this item is obtained by inverting the figure selected by the patient on the analogue-visual scale of Card 2: e.g. when a value of 2 is selected on the Card, this is equivalent to a score of 4 for this item, and so on, for each of the other items).

4a. Frequency of a subjective OWS

Some people taking doses of methadone experience withdrawal symptoms such as anxiety, restlessness, irritability, difficulty in sleeping, tiredness, shivering, muscular aches and lack of appetite. These are symptoms that other people you are with generally cannot see.

During the last seven days, how frequently have you felt any of these symptoms?

- There are people receiving treatment with methadone who do not experience any serious withdrawal symptoms, but who nevertheless do not feel well. During the last seven days, have you felt any symptoms like ... or ...? (at this point repeat to the patient the symptoms listed in the main question).
- If you have, on how many of the last seven days did you have these symptoms?

(To determine the presence of a subjective OWS clinically, the patient must present two or more

of the symptoms listed in the main question, unless the interviewer identifies some other clinical condition of the patient that provides clearer confirmation of a subjective OWS.)

- On none of the last seven days.....5.
- On one or two of the last seven days.....4.
- On three to six of the last seven days.....3
- On each of the last seven days, once or twice a day.....2
- On each of the last seven days, more than twice a day or very often.....1.

>>>> CUT-OFF POINT: If a patient has not presented any two of these symptoms at any time during the last week (score 5 in questions 4a and 4b), pass directly to question 5a.

4b. Intensity of a subjective OWS

During the last seven days, how intense, on average, were the withdrawal symptoms you say you felt?

- *On the occasions when you felt these symptoms, how intense were they, on average?*

Show the patient CARD 2.

Score: ___/ (The score for this item is obtained by inverting the figure selected by the patient on the analogue-visual scale of Card 2: e.g. when a value of 5 is selected on the Card, this is equivalent to a score of 1 for this item, and so on, for each of the other items).

5a. Frequency of craving for heroin

During the last seven days, how frequently have you felt an urgent need to use heroin?

- *During the last seven days have there been times when you desperately wanted to take heroin?*
- *If there have, on how many of the last seven days did you feel these needs?*
 - On none of the last seven days 5.
 - On one or two of the last seven days..... 4.
 - On three to six of the last seven days..... 3.
 - Once or twice every day..... 2.
 - Three or more times every day..... 1.

>>>> CUT-OFF POINT: If a patient has not felt any craving for heroin at any time during the last week (score 5 in questions 5a and 5b), pass directly to question 6a.

5b. Intensity of craving for heroin

During the last seven days, how intensely did you feel the need to use heroin, on average?

- *On the occasions when you wanted to take heroin, how intensely did you feel this need, on average?*

Show the patient CARD 2.

Score: ___/ (The score for this item is obtained by inverting the figure selected by the patient on the analogue-visual scale of Card 2: e.g. when a value of 4 is selected on the Card, this is equivalent to a score of 2 for this item, and so on, for each of the other items.)

6a. Frequency of overmedication

Some people who take doses of methadone experience symptoms such as feeling sleepy or sedated, difficulty in speaking, being unusually active or, alternatively, the sensation of “being drugged”. During the last seven days, how frequently have you had any of these symptoms?

(Ask the patient specifically if he or she had felt these symptoms about 3 hours or more after having taken the dose of methadone.)

- *During the last seven days, were there any days when you had symptoms such as ... or ..., especially 3 hours or more after having taken your dose of methadone? (at this point repeat to the patient the symptoms listed in the main question).*
- *If there were, on how many of the last seven days did you have those symptoms?*
 - On none of the last seven days..... 5.
 - On one or two of the last seven days.....4.
 - On three to six of the last seven days.....3.
 - On each of the last seven days, once or twice a day.....2.
 - On each of the last seven days, more than twice a day or very often..... 1.

>>>> CUT-OFF POINT: If a patient did not have any of these symptoms at any time during the last week (score 5 for questions 6a and 6b), pass directly to an assessment of the Additional Items.

6b. Intensity of the overmedication

During the last seven days, how intense, on average, were the symptoms you say you had, in answer to the last question?

- *On the occasions when you had those symptoms, how intense were they, on average?*

Show the patient CARD 2.

Score: ___/ (The score for this item is obtained by inverting the figure selected by the patient on the analogue-visual scale of Card 2: e.g. when the value of 1 is selected on the Card, this is equivalent to a score of 5 for this item, and so on, for each of the other items.)

ADDITIONAL ITEMS

A. Patient's subjective assessment of how adequate their current methadone dose feels.

To what extent do you feel that the methadone dose you have been taking during the last seven days is adequate for you? By "adequate dose" we mean a "holding" dose that leaves you feeling "covered" (without any withdrawal symptoms), a dose that leaves you without too much of an urge to use heroin, and that at the same time leaves you not feeling too drugged.

Show the patient CARD 3.

Score: __/

B. Patient's wish to modify their dose of methadone

What dose of methadone would you like to take during the next seven days? (indicate one of the following)

- The patient wants to continue with the same dose.
- The patient wants to increase the dose to __ mgrs/day.
- The patient wants to reduce the dose to __ mgrs/day.

C. Secondary effects of the methadone taken during the last seven days

During the last seven days, have you had any of the following symptoms, at any time? (read them out to the patient). Indicate with an X those that the patient confirms.

	YES	NO
Constipation		
Increased sweating		
Insomnia, or difficulty in sleeping		
Alteration of sexual function		
In women, menstrual alterations		
Tiredness/muscular aches or pains		

D. Concomitant medication taken during the last seven days

Active drug	Total daily dose

E. Degree of general functioning of the patients (DSM-IV GAF)

ODAS - ANNEXES

CARD 1:

On this scale from 1 to 5, indicate how you perceived or felt the effect of that dose of heroin (or those doses of heroin).

It had no effect at all on me

The effect was extremely intense

1

2

3

4

5

CARD 2:

On this scale from 1 to 5, indicate the degree of intensity you felt.

Nothing at all

Extremely intense

1

2

3

4

5

CARD 3:

On this scale from 1 to 5, indicate to what extent you feel that the dose you are taking is adequate for you. How OK is the dose?

Totally inadequate, useless

Perfectly adequate, OK.

1

2

3

4

5