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Initiating Opioid Substitution Treatment: A Comprehensive Guide for General Practitioners

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Abstract **Review Article**

The article "Initiating Opioid Substitution Treatment: A Comprehensive Guide for General Practitioners" is a review intended to guide GPs in managing opioid dependence using opioid substitution treatment (OST). OST, which primarily involves methadone and buprenorphine, aims to help patients achieve stability and recovery by substituting illicit opioids, thereby reducing withdrawal symptoms and cravings. The article stresses the multifaceted nature of drug misuse patients, emphasizing the need for a thorough assessment. This assessment should cover the patient's substance use history, medical and mental health background, current medications (paying close attention to interactions with drugs like gabapentin and pregabalin), the risk of overdose and medication diversion, collaborative treatment planning with the patient, prior treatment experiences, information from support networks, physical examination findings, and social circumstances. Initiating OST requires a credible account of recent, substantial opiate use, confirmation through drug tests, and observable withdrawal signs, potentially evaluated with the COWS score. Patient safety is paramount during the initiation phase, recommending low starting doses with gradual increases under direct observation to prevent overdose. The stabilization phase involves adjusting the dosage based on individual needs by experienced prescribers, who must distinguish between toxicity and withdrawal symptoms. Long-term maintenance includes continuous monitoring, addressing any ongoing illicit drug use, providing comprehensive psychological and social support, and collaborating with specialists when necessary. The guide also outlines important aspects of safe prescribing, the conditions under which prescriptions may be suspended or discontinued, and critical safety measures related to high-risk periods like treatment initiation and release from incarceration, potential drug interactions, preventing diversion, and managing concurrent substance use. A case study exemplifies these principles, and the key takeaways underscore OST's effectiveness in reducing mortality and enhancing quality of life, the necessity of comprehensive assessment, the importance of cautious initiation, prioritizing patient safety, managing diversion risks, and the value of sustained support for recovery.

Keywords: Opioid Substitution Treatment, OST, Methadone, Buprenorphine, Opioid Dependence, General Practitioners, Assessment, Initiation, Patient Safety, Diversion.

INTRODUCTION

Opioid substitution treatment (OST) is a cornerstone in the management of opioid dependence, the aim of which is to try to induct the individual patient into a pathway that moves towards stability and recovery.

Patients with drug misuse problems are often very complex and have a myriad of problems, which can involve medical complications of drug use, the social impact of illicit use and often, a forensic history to fund their habit.

This is why it is important to look at the patient holistically, understand their place in the family unit, map the support networks, and also be aware of children that they may be responsible for.

Increasingly, GPs are becoming more involved in prescribing OST in the community and prison settings. The entry requirement is relatively low, sometimes starting clinics after a one-day training session to obtain RCGP part one.

The nuances and potential pitfalls in this area cannot be covered in this manner, and it is vital that somebody starting to prescribe OST is aware of the

limits and has a senior colleague that they can call upon for complicated cases.

In this article, we hope to establish the benefits of OST, talk about the dangers of prescribing in certain situations, and hopefully avoid fatalities.

Understanding Opioid Substitution Treatment

OST involves a prescription of controlled opiates, namely methadone and buprenorphine. We are replacing an illicit opiate, for example, heroin, with a prescribed opiate, thereby reducing opioid withdrawal symptoms and cravings and reducing the reliance of the patient on illicit substances.

Methadone is a synthetic opioid agonist that was invented by the Germans in World War II primarily as a painkiller. The most common form used today is a green emerald elixir liquid, which has a very long half-life of around 24 to 36 hours and is given as a once-a-day dose.

The pharmacokinetics of methadone is quite complicated, which makes linear conversions from other opiates difficult; it is lipophilic and absorbed in the body's fat stores, for this reason, the plasma levels on induction can continue to rise with the same daily dose being consumed.

Buprenorphine is a partial opioid agonist; however, it binds avidly to opioid receptors, much stronger than all other opioids. This binding is so strong that even naloxone cannot displace it. Since it is a partial agonist, death by respiratory depression is less common than with methadone if taken correctly.

In secure settings, it is given as a wafer that melts sublingually to avoid diversion and selling on the black market, when misused, it is crushed and snorted.

Recently, buprenorphine injections, given intramuscularly, are becoming more widespread. The advantage here is that they can be given weekly or monthly, allowing the individuals a near-normal life without having to attend daily for an OST dose.

The principle of saturating the opioid receptors with buprenorphine is that it would block any illicit use.

Other drugs and combinations are used worldwide; however, these are the ones commonly used in the UK.

Assessment and Evaluation

Prior to initiating OST, a thorough assessment is paramount to ensure patient safety and tailor treatment to individual needs. This assessment should encompass several key areas:

- **Comprehensive Substance Use History:** Obtain a detailed history of the patient's opioid use, including the types of opioids used, frequency, amount, and route of administration (i.e., oral, IV, or inhalation). Additionally, gather information about other substance use, such as alcohol, benzodiazepines, and stimulants, as these can significantly impact treatment decisions. If the patient is regularly injecting, we must look at the injection site for signs and symptoms of deep vein thrombosis, cellulitis, and auscultate for infective endocarditis.
- **Medical and Psychiatric History:** It is very common to have concurrent mental health problems. It is often difficult to ascertain whether the psychiatric problems led to drug addiction or the use of drugs was to mask the psychiatric problem; in either case, we must treat the addiction with mental health support to achieve the best outcomes.
- **Medication Review:** Understand all medications and substances the patient is using, especially drugs like gabapentin and pregabalin, that can potentiate the effects of methadone and respiratory depressants. Prescribe lower OST doses during initiation in these cases. Be particularly wary if the patient is on two potentially respiratory depressant medications. Overdose with methadone is unusual when methadone is the only medication being taken.
- **Risk Assessment:** Identify immediate risks, such as potential overdose risk, injecting-related harm (e.g., HIV or hepatitis C transmission), and other urgent concerns. Assess the patient's risk of diversion, which involves the transfer of prescribed medication to others for illicit use. Diversion and trading medication is a high-risk activity for the community.
- **Shared Decision-Making:** Engage the patient in a collaborative discussion about treatment options; as the patient is not happy with the choice of treatment, then the patient is more likely to come "off script" and engage in illicit drug taking. The patients will often try to goad you into prescribing high doses and it can be difficult to keep the patient engaged and not capitulate to the requests without a sound clinical reason. The prescriber must always be able to justify the rationale for increasing OST.
- **Treatment History**: It is important to understand if a patient has had previous treatment episodes, what worked, and what didn't.
- **Collateral Information:** With the patient's consent, gather information from family, carers, and other involved professionals to develop a more comprehensive understanding of their situation.
- **Examine the Patient**: Look for signs of intravenous drug use, malnourishment, and poor self-care.
- **Social History**: Ask about support networks particularly if they have children.

Initiating OST: A Phased Approach

When deciding on initiating OST, the patient must fulfil certain criteria.

1. They must have a plausible narrative; they must be taking regular opiates in a significant quantity and have taken them recently. It would be dangerous to prescribe OST to someone who is opiate naïve. We have seen deaths in cases where OST was started in people who had only taken heroin occassionally.
2. There must be objective evidence of opiate use, which is usually confirmed with a drug screen to confirm the presence of opiates.
3. The subjective evidence must match the narrative, so, for example, a patient who is a heavy heroin user is arrested and presents to police custody and should be showing signs of opiate withdrawal if they have not had drugs for most of that day. A medical practitioner can assess the scale of opiate withdrawal using the COWS score.

SWEATING: Over past 1/2 hour not accounted for by room temperature or patient activity	0 - pulse rate 80 or below 1 - pulse rate 81-100 2 - pulse rate 101-120 4 - pulse rate greater than 120
GI UPSET: Over last 1/2 hour	0 - no GI symptoms 1 - stomach cramps 2 - nausea or loose stool 3 - vomiting or diarrhea 5 - multiple episodes of diarrhea or vomiting
SWEATING: Over past 1/2 hour not accounted for by room temperature or patient activity	0 - no report of chills or flushing 1 - subjective report of chills or flushing 2 - flushed or observable moistness on face 3 - beads of sweat on brow or face 4 - sweat streaming off face
TREMOR: Observation of outstretched hand	0 - no tremor 1 - tremor can be felt, but not observed 2 - slight tremor observable 4 - gross tremor or muscle twitching
RESTLESSNESS: Observation during assessment	0 - able to sit still 1 - reports difficulty sitting still, but is able to do so 3 - frequent shifting or extraneous movements of legs/arms 5 - unable to sit still for more than a few seconds
YAWNING: Observation during assessment	0 - no yawning 1 - yawning once or twice during assessment 2 - yawning three or more times during assessment 4 - yawning several times/minute
PUPIL SIZE:	0 - pupils pinned or normal size for room light 1 - pupils possibly larger than normal for room light 2 - pupils moderately dilated 5 - pupils so dilated that only the rim of the iris is visible
ANXIETY OR IRRITABILITY	0 - none 1 - patient reports increasing irritability or anxiousness 2 - patient obviously irritable or anxious 4 - patient so irritable or anxious that participation in the assessment is difficult
BONE OR JOINT ACHES	0 - not present 1 - mild diffuse discomfort 2 - patient reports severe diffuse aching of joints/muscles 4 - patient is rubbing joints or muscles and is unable to sit still because of discomfort
GOOSEFLESH SKIN:	0 - skin is smooth 3 - piloerrection of skin can be felt or hairs standing up on arms 5 - prominent piloerrection
RUNNY NOSE OR TEARING	0 - not present 1 - nasal stuffiness or unusually moist eyes 2 - nose running or tearing 4 - nose constantly running or tears streaming down cheeks

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

In practical terms we do not encounter COWS scores over 30, historically when the strength of heroin was more potent higher scores would be encountered.

The assessment relies heavily on the symptoms related by the patient. If they are not showing signs of withdrawal, you would have to question the veracity of their usage.

4. Safety is Paramount;

You must have a healthy appreciation of the fact that you are potentially prescribing a very strong opiate; for example, 2 mg of methadone is equivalent to around 60 mg of codeine. When you consider that most people will establish themselves on around 40 mg of methadone, you understand why death can occur.

If a patient is erratic, continually found to trade medication, not comply with the rules of monitoring, and taking a deadly cocktail of illicit drugs. You would need to tread cautiously, as you can end up in Coroner's court. Pausing and discussing these cases collaboratively with colleagues is ideal.

5. Induction:

- **Start Low and Titrate Gradually:**

Begin with a low dose of either methadone (typically 10-20) or buprenorphine and increase it gradually based on the patient's response. We find that most prison facilities initiate at 10mg regardless of how much drugs a patient is using.

  - The increments should be no more than 5–10 mg daily, with total weekly increases generally not exceeding 30 mg above the starting dose.

- **Prioritise Safety:**

It's critical to remember that while withdrawal is uncomfortable, overdose can be fatal. Educate patients about the signs and symptoms of opioid toxicity and the importance of seeking immediate medical attention if they experience any concerning symptoms.

- **Supervised Consumption:**

Most new patients require directly observed therapy (DOT) for a period to monitor progress and assess risk. We must ensure the patient is taking their OST and not trying to sell it. The pharmacist usually will be visually watching the patient swallow the methadone and drink a glass of water afterward, or in the case of buprenorphine, will ensure that the tablet has dissolved completely under the tongue.

6. Stabilisation:

- **Individualised Dosing:**

The optimal dose of methadone or buprenorphine varies widely among individuals. The goal is to reach a dose that eliminates opioid cravings and withdrawal symptoms without causing excessive sedation or other adverse effects.

- **Experienced Prescribers Only:**

Decisions about dose adjustments during the stabilisation phase should be made by experienced prescribers with expertise in managing opioid dependence. It is important to be able to differentiate between toxicity and withdrawal; some symptoms overlap, e.g., stomach pain and nausea; however, withdrawal symptoms tend to be worse before the dose of OST is given, and toxicity symptoms occur post-dose. Occasionally, patients will mistake their toxicity symptoms for withdrawal and push for an increment in their OST dose, which can prove fatal if actioned.

If a patient is looking drowsy, you will likely need to withhold the OST and evaluate the patient.

- **Missed Doses:**

If a patient misses three or more consecutive doses, reassess them before restarting treatment. An urgent, face-to-face consultation is usually required. When three days' supply has been missed, the patient should be reassessed before receiving further doses. Missed doses can lead to a loss of tolerance and continuation at the same dose can lead to overdose.

7. Maintenance:

- **Long-Term Support:**

OST is often a long-term treatment, and patients may require ongoing support to maintain stability and achieve their recovery goals.

- **Regular Monitoring:**

Continuously assess the patient's response to OST, including their adherence, stability, and improvement in functionality in life as a whole. Always ask about illicit drug use and screen occasionally with random urine screens.

If they are using illicitly, then you must first consider if it is safe to continue OST. If you feel that the patient is taking illicit drugs because they are underdosed, then you may consider increasing the OST dose; these decisions are taken by experienced practitioners with careful consideration and documentation.

- **Wrap-Around:**

The patient's psychological, medical, and social needs need to be considered, and so a wraparound service with appropriate referrals gives the best outcome; ideally, services will have onsite support as a one-stop shop.

- **Feasibility**:

Research indicates that methadone treatment in primary care settings can be as effective as in specialist drug clinics.

- **Training:**

Appropriate training enables GPs to effectively manage patients receiving OST. The entry requirement is RCGP Part 1. We personally feel that this training does not adequately prepare a practitioner to understand the pitfalls, and supervised training is essential before working solo. The RCGP Part 2 is a 6 months undertaking, it does give a good idea of the theory but unfortunatley little practical application of working in the field.

- **Collaboration**: Work with specialist services for complex cases or when additional support is needed.

- **Patient Safety:**

Educate patients regarding safety around taking treatment, advise about losing tolerance, and the risk of overdose. If a patient is incarcerated for any length of time or has an absence of drugs, then resuming the habit at the previous dose can lead to a fatal overdose.

- **Integrating Services:**

Make sure that the initial assessment, registration, and start of prescribing and psychosocial interventions are all done in the same place. Also, make sure that recommended evidence-based psychosocial and pharmacological treatments are always available.

Safe Prescribing Boundaries

Clear communication about prescribing safety is needed. Prescribers should clearly communicate the criteria used to determine the safety of ongoing prescriptions and when changes are necessary to manage documented risk.

Suspension and Exclusion

Following a thorough risk assessment involving the prescribing clinician and multidisciplinary team, it may become necessary to suspend or withdraw a prescription.

Pitfalls and Safety Measures

Several factors can increase the risk associated with OST and require careful attention:

- **Increased Risk Period:**

Most deaths occur in the first week of initiation due to a lack of tolerance; they also occur when a prisoner is released back into the community, and they continue the previous habit, having lost tolerance during incarceration.

- **Medication Interactions:**

Be vigilant about potential interactions, especially with gabapentin and pregabalin. These drugs potentiate the effect of OST; be cautious when prescribing OST against two or more psychotropic respiratory depressants.

- **Low Doses:**

Exercise caution with lower methadone doses, as they may be less effective. If a person is inadequately dosed, then they are more susceptible to using illicit drugs, which puts them in harm's way.

- **Diversion**: Enforce supervised or interval dispensing to reduce the risk of diversion and overdose deaths.

- **Substance Use in Prisons:**

The easiest way to get drugs in prison is to consult a prison doctor with fictitious symptoms. Prescribing gabapentin or opiate painkillers should be carefully monitored.

- **Alcohol and other substances:**

Treatment for alcohol misuse and advice against using cannabis and other illicit substances should be in place as appropriate. There may be instances where the practitioner will have to manage alcohol withdrawal as well as the opiate withdrawal simultaneously.

- **Tertiary in Patient Units:**

We may need to admit the patient to hospital if they are medically unwell e.g. septic from infection or have delirium tremens from alcohol withdrawal, there are also tertiary units where a patient can be admitted if they have complicated presentations requiring in patient care.

Clinical Case Scenario

A 35-year-old patient, recently released from prison, requests OST. They have a history of heroin use and report recent relapses. The patient also mentions taking prescribed gabapentin for nerve pain. How should you assess and initiate OST in this situation, considering the potential risks and interactions?

This scenario highlights several key considerations:

1. Risk Assessment: Prioritise a comprehensive risk assessment, including a detailed substance use history, medical and psychiatric history, and assessment of potential overdose risk and diversion risk.
2. Medication Interactions: Be aware of the potential interaction between gabapentin and methadone, which can increase the risk of respiratory depression. Consider prescribing a lower initial dose of methadone and closely monitor the patient for signs of sedation or respiratory depression.
3. Drug test to confirm the opiate and screen for other illicit substances, the UDS (urine drug screen) will be able to detect a number of substances

The urine drug screen will be able to detect opiates, methadone, buprenorphine, benzodiazepine, cannabis

1. **Establish Tolerance:** If the patient has only been taking drugs for a few weeks, they may be opiate naive, in these cases, treating the withdrawals symptomatically with eg paracetamol, metoclopramide (antiemetic), mebeverine (antispasmodics) may be the safer option, if you consider initiating OST, start low and increase slowly.
2. **Supervised Consumption:** When initiating OST always co-ordinate with the pharmacist to ensure supervised consumption of methadone to ensure adherence and reduce the risk of diversion.
3. **Psychosocial Support:** Offer counselling and other psychosocial support services to address the patient's underlying issues and promote long-term recovery.
4. **Linkage to Community Resources:** Connect the patient with community-based support services, such as housing assistance, employment training, and peer support groups, to facilitate their reintegration into the community.

Key Points

- OST reduces mortality and improves the quality of life for opioid-dependent patients.
- A thorough assessment, including substance use history and potential medication interactions, is crucial.
- Initiate OST with low doses, gradually titrating based on individual response.
- Prioritise patient safety through education, monitoring, and collaboration with specialist services.
- Address diversion risks with supervised dispensing.
- Support patients' recovery goals with ongoing review and psychosocial support.

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Additional Resources

- NICE Guidance: http://www.nice.org.uk/
- Essential Cochrane Reviews: www.cochrane.org/reviews
- Home Office Licensing Section: DFLU.ie@homeoffice.gsi.gov.uk
- Form for travelling with controlled drugs: www.gov.uk/travelling-controlled-drugs
- Pharmaceutical Care for Patients Prescribed Opioid Replacement Therapy (NHS Scotland 2015).
- Access to supervised doses of opioid substitution for people in police custody (PHE 2015).