Treatment Protocol Review

Puget Sound Psychiatric Center (PSPC) SUBOXONE TREATMENT PROTOCOL (PSTP): Out-patient SUBOXONE Induction, Maintenance and Taper for Opioid-Dependent Adults

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ABSTRACT:

The Puget Sound Psychiatric Center has been using SUBOXONE for the treatment of Opiate Dependence for many years. Over the years the PSPC SUBOXONE TREATMENT PROTOCL (PSTP) has evolved into its currents form. A vast majority of patients have enjoyed huge successes by following this structured and easy to follow treatment protocol. The objective of this paper is to outline the PSPC SUBOXONE Treatment Protocol (PSTP), currently used in clinical practice at the Puget Sound Psychiatric Center (PSPC). The PSTP, is based broadly off the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction Treatment Improvement Protocol (TIP– 40) a publication of the USDA SAMHSA. The current version of the treatment protocol went through a number of evolutionary changes in the past decade or so, to come to its current version. In its current state of the art form, it is a formidable protocol. However, it is expected that as our knowledge regarding opiate addiction, as well as comorbidities improves we will further improve our protocols. As in other treatment centers, it has also been observed at our opiate dependence treatment center that patients who have opiate dependence have better outcomes with a structured protocol. Another item that was of great clinical importance was the observation that patients who are in regular meaningful psychotherapy have a much better overall response to the treatment protocol. The outcome measures of the treatment protocol (which are beyond the scope of this article) were determined through relapse rates (RR) within one year of starting the protocol, and the time to relapse (TTR) after start of the treatment protocol. It is the experience of the author that this protocol has been easy to use in clinical practice. It is also the opinion of the author that results seen when using this protocol are at least equal to, if not better than any other treatment protocol currently in use.

INTRODUCTION:

SUBOXONE for the treatment of Opiate Dependence, is recognized as an important addition to the repertoire of the treatment options. Yet, at the same time, there have been many struggles faced by SUBOXONE prescribing physicians, mainly because of the absence of a well-established universally accepted SUBOXONE Treatment Protocol.

Over the years numerous variations to the SAMHSA TIP -40 (TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction; SMA07-3939, 09/2004) guidelines have been proposed and used by different SUBOXONE prescribing physicians. The presence of so many, similar albeit differing treatment protocols prompted the author at the Puget Sound Psychiatric Center, to formulate a simple to understand and easy to implement treatment protocol, best suited for the needs of the PSPC and the patient population that we help.

The starting point of the Treatment Protocol, was the recognition that any Chemical Dependency treatment protocol has to be well structured, with minimal discretionary changes allowed; including the timing of the follow-up appointments, participation in therapy and the dosing by the treating physician.

PSTP has incorporated structure as the main modality in the Treatment protocol. Also incorporated in the treatment protocol along-with mandatory therapy, was the equally important mandatory abstinence of all other substances including THC, and disallowing use of Benzodiazepines.

In a structured approach the patients who come for treatment, as well as the clinicians prescribing and administering treatment are all aware of the protocol; also the expectations from the prescribers, as well as the patients are very clear and it is very rare that a deviation would occur because of some misunderstanding.

It is to be clarified that deviations from the protocol can and do happen on occasions, but this is the exception and not the rule. Any deviations from the protocol are on a case by case basis, and for only the best clinical interest of the patient.

We are cognizant that patients who have Opiate Dependence, and come for treatment with SUBOXONE can be confused and even disoriented in treatment settings and may not be able to follow complex protocols. We are also aware that some patient on the other hand may have manipulative or even abrasive behaviors. In many instances, patients with opiate dependence have been using various forms of opiates for long durations, sometimes at high dosages. A common concern that comes across from many patients is that do not want to go through painful withdrawals. Psycho-education, it is extremely important to educate and inform the patient about their condition and to continue to do so throughout the course of their treatment. It is equally important to encourage the patient to ask questions, vent their concerns about the process and be actively involved in their treatment process.

The PSTP also works with the assumption that most if not all patients with Opiate Dependence (American Psychiatric Association DSM-5, 2014) have co-occurring

psychiatric conditions, which need to be assessed and treated appropriately, even though use of medications may not be necessary for all such co-occuring conditions.

Our current treatment protocol (PSTP) has been in use for the past almost a decade at the Puget Sound Psychiatric Center with remarkable success. We have noticed that not only have the relapse rates within the first year gone down, but also the time to relapse has dramatically been prolonged as well. In addition to this, the Patient Reported Quality Of Life Assessment (PRQOLA) indicates that the patient's have better self-esteem, less symptoms such as related to mood, anxiety, sleep , and attention: majority of patients also reported improvement in relationship issues (significant others, offsprings, parents, peers, and coworkers).

Phases of PSTP:

Phase 1: Patient Selection & Evaluation.
Phase 2: Induction & Titration of SUBOXONE.
Phase 3: Stabilization Phase on SUBOXONE.
Phase 4: Maintenance Phase on SUBOXONE.
Phase 5: Titration & Discontinuation of SUBOXONE.
Phase 6: Follow-up.

PHASE 1: Patient Selection & Evaluation.

The most important aspect of any protocol and its success hinges on appropriate patient selection followed by an even more exhaustive Evaluation process. The Evaluation process not only includes determining treatment goals, objectives and modalities for the patient, but also evaluating the person for appropriateness of inclusion in the protocol.

A number of things are considered when we are contacted by potential patients.

It is very appropriate for patients to either a referral for a SUBOXONE treatment facility or to “Google search” for doctors in the area listed on the “SUBOXONE website”. Frequently patients/potential patients call a number of clinics and doctors listed on that website trying to get in for the earliest appointment time. Patients also want to consider the cost commitment, and want a easy to follow treatment protocol.

Unfortunately the sad news for many patients is that SUBOXONE treatment is not easy or is not as convenient as they would want it to be.

The recommendation of the US DHHS SAMHSA TIP–40, and the DEA expectations, mean that every patient on SUBOXONE should be provided the opportunity of therapy.

Patients call and try to negotiate protocols, sometimes mentioning that there are doctors who only require the patient to come, hand over the money and walk out with a prescription of SUBOXONE.

Whenever I hear such a statement, I take it with a grain of salt, knowing that many patients would want to find the least inconvenient way of getting the treatment that they think they want.

There are also instances, when patients call to inquire about SUBOXONE protocol, and become irritated about not getting “good customer service”, after being informed of the protocol requirements and expectations. There obviously are some concierge establishments which offer a customized almost gourmet treatment menus for their “clients”; however I am not aware of any these facilities publishing data or for these establishments having a better outcome than any regular treatment facility.

I have heard about irate patient who wants the so-called “combo number one” of “only SUBOXONE.”

A person who is impatient, impulsive, demanding and perhaps even somewhat entitled might indeed be deserving of SUBOXONE treatment, however management of such a person can be challenging. Therefore for the treatment to be successful for such patients, these issues need to be discussed in detail in therapy.

In this day and age of rising expectations of physician productivity, I still recommend that patient needs to be thoroughly screened for appropriateness of inclusion into a treatment protocol. It is important for the treatment facilities to identify patients that can be best served therapeutically and ethically. And not to take on patients to fulfill management imposed quota requirements.

This is not to say that all patients do not deserve our full expertise equally, however this is to acknowledge the limitations of individual clinics.

Therefore, it is extremely important to keep in mind that patient selection is extremely important.

Once patient selection has been completed. We go to the second part of the first phase, i.e. a comprehensive evaluation.

It is important to explore many details about the patient's history. A thorough history gives us a good insight into the patients psychological predisposing, precipitating and perpetuating factors. In the evaluation process co-occurring substance use and dependency issues, as well as co-occurring psychiatric co-morbidities also need to be given due consideration.

Initial laboratory and toxicology examination is also completed at this time.

When satisfied that the patient is a good faith participant in treatment, the patient has been evaluated for psychiatric and co-occurring chemical dependency issues; and laboratory and toxicology examination do not exclude the patient from participating in treatment, psycho-education is begun, with a thorough explanation of the protocol and what to expect. As the patient gives consent to start treatment, the patient is told to abstain from all substances, especially OPIATES. All other substances, such as Benzodiazepines, etc. are also not allowed.

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PSPC Suboxone Treatment Protocol

Phase	Event	symptoms	Status of Opiate Use	time line	Medication Management			Therapy (As Clinically Appropriate)				
					Rescue Medications	Psych Meds	SUBOXONE					
Evaluation	Point of first Contact with Clinic	No Symptoms	Actively Using	Evaluation Day 1	Not Required, but available if requested	Yes, If needed	No SUBOXONE	Psycho-Education	Supportive Therapy	Motivational Therapy	Psychotherapy	Support Groups
Abstinence	Before start of Induction	Partial Withdrawal Symptoms	Advised to Refrain from Use	SUBOXONE Day -7 to -1	Rescue Medications Started	Yes, If needed	No SUBOXONE	Initiated	Initiated	No Initiated	Not Initiated	Recommended
Induction	Start of SUBOXONE and titration up	Partial Withdrawal Symptoms Improving	Advised to Refrain from Use	SUBOXONE Day 01 to Day 4	No Rescue Medications Continued	Yes, If needed	SUBOXONE Titration upto 8 mg / day	Continued	Continued	Initiated	Not Initiated	Recommended
Stabilization	Continue SUBOXONE, slight adjustment of dose if needed	No Physical Symptoms, Some Psychological Symptoms	Advised to Refrain from Use	SUBOXONE Day 05 to Day 30	Not Required, but available if requested	Yes, If needed	SUBOXONE Adjustment from between 4 mg /day upto 12 mg / day	Continued	Continued	Continued	Initiated	Recommended
Maintenance	Continue SUBOXONE, at stable dose	No Physical Symptoms, Some Psychological Symptoms	Advised to Refrain from Use	SUBOXONE day 31 to Day 365 +/- 90 Days	Not Required, but available if requested	Yes, If needed	SUBOXONE Medication at Stabilization Dose	Continued	Continued	Continued	Continued	Recommended
Taper	SUBOXONE Titrated down slowly	No Physical Symptoms, Some Psychological Symptoms	Advised to Refrain from Use	End of Maintenance Phase + 120 days	Rescue medications, if needed and requested by patient	Yes, If needed	SUBOXONE Taper; at a rate of 2 mg drop in daily dose per month	Continued	Continued	Continued	Continued	Recommended
Follow-Up	No SUBOXONE	No Physical Symptoms, Some Psychological Symptoms	Advised to Refrain from Use	End of Active SUBOXONE Phase +90 Days	Not Required, but available if requested	Yes, If needed	No SUBOXONE	Continued	Continued	Continued	Continued	Recommended

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The patient is then started on a “RESCUE MEDICATION COCKTAIL”. The Cocktail includes; NEURONTIN 100 mg TID; SEROQUEL 50 mg QHS; Clonidine 0.1 mg TID, Baclofen 10 mg BID (for a maximum of 5 Days); and if needed for Diarrhea LOMOTIL is prescribed at a max of 4 doses over 48 hours.

Psycho Education and Supportive Therapy is initiated during this phase.

Random Toxicology test can be performed, to confirm presence of SUBOXONE, absence of OPIATES BENZODIAZEPINES and other substances

Phase 2: Induction & Titration of SUBOXONE.

Once the patient has started to exhibit symptoms of partial withdrawal from opiates (SUBOXONE Day 1), as evidenced by the Clinical Opiate Withdrawal Scale (COWS) (Wesson DR, 1999), which can be within 24-48 hours (1-2 days) of the last use of short acting opiates or as long as upto 168 Hours (7 days) from the last use of a long acting opiates, the first dose of SUBOXONE 2mg/0.5mg is given, the next day (SUBOXONE Day 2) the patient is given a dose of SUBOXONE 4 mg/1mg. On SUBOXONE Day 3, a SUBOXONE dose of 6 gm /1.5 mg is given. On SUBOXONE Day 4, the patient is given SUBOXONE 8 mg /2 mg.

During these four days, the patient is encouraged to continue to take the Rescue Medication Cocktail.

Regular weekly Supportive Therapy and Psycho-education is continued, and Motivational Therapy is started. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances.

Random Toxicology test can be performed, to confirm presence of SUBOXONE, absence of OPIATES BENZODIAZEPINES and other substances

Phase 3: Stabilization on SUBOXONE.

Once the patient has successfully progressed beyond the Induction and Titration Phase, during the next 3 weeks, the patient has an appointment every 1-2 week for evaluation and assessment of the medications dose, his response to the medication, his commitment to abstinence and also to address co-morbid psychiatric concerns.

It is during this phase that the dose of SUBOXONE may be adjusted from the 8 mg/ 2 mg daily dose to as low as a dose of 4 mg/1 mg daily to as high as 12 mg / 3 mg daily dose, depending on the patient clinical and subjective response and tolerability.

Supportive Therapy, Psycho-education, and Motivational Therapy are continued. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances. Psychotherapy is initiated. Random Toxicology test are be performed, to confirm presence of SUBOXONE, absence of OPIATES BENZODIAZEPINES and other substances.

Phase 4: Maintenance on SUBOXONE.

This is the longest of the treatment phases, and usually lasts approximately 12 months (+/- 3 months). During this period the patient continues on the same dose of once daily SUBOXONE that was established during the Stabilization phase. Patient is evaluated at least once a month by the prescribing physician. Regular monthly and unscheduled random toxicology tests are performed, to confirm presence of SUBOXONE, absence of OPIATES, BENZODIAZEPINES and other substances.

Co-occurring psychiatric and other substance use issues are actively treated.

Regular weekly Supportive Therapy, Psycho-education, Motivational Therapy and Psycho-therapy are continued. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances.

Phase 5: Titration & Discontinuation of SUBOXONE.

At the successful completion of Phase 4, the patient goes into a slow titration phase. The dose of SUBOXONE is decreased every month by 2 mg/0.5 mg daily dose increments, till the final month. In the last month the dose of SUBOXONE is decreased by 1 mg/0.5 mg every 15 days. E.g. if the patient had entered Phase 5 on a daily dose of 8 mg/2 mg, then in three months he would be completely weaned off..

Co-occurring psychiatric and other substance use issues are actively treated.

Regular weekly Supportive Therapy, Psycho-education, Motivational Therapy and Psycho-therapy are continued. The patient is also encouraged to join a support group. Patient is advised to maintain abstinence from all substances.

Patient is evaluated at least once a month by the prescribing physician. Regular monthly and unscheduled random toxicology tests are performed, to confirm presence of SUBOXONE, absence of OPIATES, BENZODIAZEPINES and other substances

Phase 6:Follow-up.

90 days after successful completion of the SUBOXONE protocol, the patient is contacted for follow-up. Patient is assessed and evaluated.

Patient is advised to continue Motivational Therapy and Psycho-therapy. The patient is also encouraged to maintain connection with a support group. Patient is advised to maintain abstinence from all substances.

CONCLUSION:

As has been referenced previously in this article, it is very important at very beginning to establish a good therapeutic alliance with the patient.

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For the success of the treatment it is important, to establish at the very beginning, a good therapeutic alliance with the patient. Therapeutic alliance should mean not only establishing boundaries with the patient, but also at the same inculcating a therapeutic bond of mutual respect between the clinician and the patient. The therapeutic alliance is based on the best clinical interest of the patient, while adhering to the principles of medical practice and care of the patient at its highest regard.

The clinical determination of whether the patient is in partial withdrawals can be aided by the use of COWS (Clinical Opiate Withdrawal Scale) (Wesson DR, 1999), sometimes patients are asked to report their experiences by filling out SOWS (Subjective Opiate Withdrawal Scale) (Handelsman et al, 1987).

Using these two scales together gives us some level of reliability and correlation of validity of the subjective opiate withdrawal scale. It is well accepted that many with opiate dependence issues tend to exaggerate the extent and frequency of their use, as well as the symptoms that they experience. Using the clinical opiate withdrawal scale (COWS) may give us an objective assessment of what the patient may be experiencing.

It is to be noted that there are some clinics, which use COWS in determining the dose of SUBOXONE for the induction and maintenance phases, the PSTP does not utilize cows to determine the dose of SUBOXONE that used for induction or maintenance. Our dose range strictly kept between 8mg/2mg to 12mg/3mg per day.

The support groups such as AA and NA, serve a vital and important function in the recovery process of the patients. However, they are no substitute for regular and ongoing chemical dependency/mental health psychotherapy.

Lastly, an essential part of the treatment protocol for patients who are on SUBOXONE is the fact that they need to be financially responsible for not only their appointments, but also their missed appointments. Patients who have chemical dependency issues tend to have a history of irresponsible actions, not only financially, but also in their judgment regarding use of substances, and management of their time. By requiring patient's to be responsible their time and money, the patients learn important skills helping them succeed in life.

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