Opioid substitution therapy with buprenorphine-naloxone during COVID-19 outbreak in India: Sharing our experience and interim standard operating procedure

Debasish Basu, Abhishek Ghosh, B. N. Subodh, S. K. Mattoo
Department of Psychiatry, Drug De-addiction and Treatment Centre, Postgraduate Institute of Medical Education and Research, Chandigarh, India

ABSTRACT

Coronavirus disease 2019 (COVID-19) has been declared as a pandemic by the World Health Organization on March 11, 2020. It has affected most countries of the world, including India. Both the disease and the unavoidable national response to it have posed unique challenges to our health-care system. A particular vulnerable group of patients is those with opioid dependence maintained on opioid substitution therapy (OST). These patients are pharmacologically dependent on the OST medication (buprenorphine, buprenorphine-naloxone combination [BNX], and methadone) for their healthy functioning and recovery. COVID-19 outbreak, lock-down, and difficult access to medical care, all are likely to induce stress and withdrawal, which is a potential risk for relapse among individuals with opioid dependence, who are anyway more vulnerable due to social, housing, living, and medical conditions. In this context, it is essential to re-strategize the existing OST services to adapt to the challenging circumstances. In this communication, we share our experience and formulate interim standard operating procedures (SOPs) for running a hospital-based OST service utilizing take-home BNX. The challenges, principles to meet the challenges, and interim SOPs are shared as being currently practiced in our center. Individual institutes, agencies, hospitals, and clinics running OST service with BNX can adapt these SOPs according to their characteristics, needs, demand, and resources; so long as, the basic principles are adhered to.

Key words: Buprenorphine-naloxone, coronavirus disease 2019, opioid substitution therapy, pandemic, standard operating procedures

BACKGROUND AND RATIONALE

Coronavirus disease 2019 (COVID-19), caused by the coronavirus severe acute respiratory syndrome coronavirus 2, was first detected in Wuhan, China in December 2019 and rapidly spread to most other parts of the world including India. It was declared as a “Public Health Emergency of International Concern” by the World Health Organization (WHO) on January 30, 2020, and further as a “Pandemic” on March 11, 2020.[1] In India, the first case of COVID-19 was detected in the last week of January 2020. The number of confirmed cases has...
been rapidly rising (more than 3000 as of this writing on April 4, 2020), with no signs of relenting as yet. The Government of India believes that, barring a few high-risk areas (or states), widespread community transmission of COVID-19 (stage 3 of an epidemic) has not started yet. As an aggressive precautionary measure to break the chain of viral transmission, the government has imposed an unprecedented whole-country lockdown since March 25, 2020, for 3 weeks as of now. The inter-state borders have been sealed to restrict nonessential movement. All modes of public transport have been shut down; all services other than essential services have been closed down. Moreover, all outpatient-based medical services (nonemergency) have been withheld for indefinite periods. Finally, some states and union territories have actually imposed a legal curfew.

Opioid substitution therapy (OST) for opioid-dependent patients is an evidence-based, effective outpatient department (OPD)-based treatment. In view of the lockdown, curfew and other restrictions on movement and supplies, a potential suspension or glitches in maintaining the OST service is a real threat. The disruption might result from limited availability of staff, difficulties in procuring the agonist medication from the manufacturers, and barriers created by the lack of transport and restricted movement to access treatment. The consequence of such disruption of service would be both immediate and far-reaching. COVID-19 outbreak, lock-down, and difficult access to medical care, all are likely to induce stress and withdrawal, which is a potential risk for relapse among individuals with opioid dependence, who are anyway more vulnerable due to social, housing, living, and medical conditions.[5–8] We suspect that the availability and access to illicit opioids and injection equipment would also be restricted under the current circumstances, which would encourage individuals to take resort to high-risk patterns of drug use (a transition from inhalational to injection route and sharing injection paraphernalia).[4] In the long run, we might expect patients to dropout from the OST, digressing from the path of recovery with serious socioeconomic and health-related complications.

In this context, it is essential to re-strategize the existing OST services to ensure the availability and access to services in the face of several structural (limited availability of human resources, restricted supply of medications) and attitudinal (fear and anxiety of health-care workers) problems.

There are a few recent guidelines from the USA[5,6] and Europe[7] regarding this and related issues, but the infrastructure, resources, regulatory provisions, and administrative procedures are different from those of our country. As such, there is an urgent need to formulate guidelines and standard operating procedures (SOP) aligned to our settings.

In this regard, we share our experience from the Drug De-addiction and Treatment Centre (DDTC), Department of Psychiatry, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, and provide interim SOPs as being currently practiced in our center. We believe our experience may help other OST facilities to reorient their OST programs according to their characteristics, priorities, needs, and resources. Further, these may also help to make decisions during future epidemics should they occur.

SHARING OUR EXPERIENCE

DDTC, Department of Psychiatry, PGIMER, Chandigarh, has been running its OST service since October 2013. In this service, selected patients with opioid dependence meeting certain selection criteria are put on buprenorphine-naloxone (BNX) sublingual tablets after obtaining written informed consent and counseling. They are examined medically and undergo appropriate investigations. They move through induction, stabilization and maintenance phases, and are provided BNX take-home doses along with group counseling sessions during the initial two phases followed by individual counseling on as-needed basis at the maintenance phase. They are dispensed BNX on a daily basis during the induction phase (about 1 week), weekly basis during the stabilization phase (about 6 months), and fortnightly basis during maintenance phase (after 6 months). If a patient misses the take-home dose for more than a month or drops out and return with relapse then they are freshly re-assessed for OST. The tablets are dispensed by a pharmacist who keeps record of the tablets dispensed with signatures of the patients. A “Recovery Model” of OST is adopted whereby each patient is periodically assessed for recovery goals in terms of abstinence from opioids and other substances, educational/vocational functioning, family functioning, social functioning, pursuing hobbies and other goals in life, and reintegration with the broader society in general. The OST clinic is run on OPD basis on Tuesdays and Wednesdays. We receive about 60–70 OST patients every Tuesdays and Wednesdays, and a trickle of patients on other working days for scheduled (government employee or other professionals on Saturdays) or unscheduled visits.

CHALLENGES FACED DURING COVID-19 OUTBREAK FOR THE OPIOID SUBSTITUTION THERAPY SERVICE

- How to run the OST service in the context of complete closure or severe restrictions on OPD functioning
- How to carry on in-person medication dispensing (in view of the fact that buprenorphine and other controlled substances under Schedule X and Narcotic Drugs and Psychotropic Substances Act are not permitted for prescription under the recently approved Telemedicine Practice Guidelines[8]
7. The registration clerk will register the patients on the
6. Everyone (including staff) will be asked to maintain a
5. The patients will be allowed to enter the (a) outer
4. For stable/maintained patients attending the OST clinic,
3. No new patients to be started on OST induction at
2. Urine testing for drugs to be suspended as of now, other
1. OST group counseling on face-to-face basis to be

PRINCIPLES TO MEET THE CHALLENGES

- Emphasize more on maintaining OST supply to those who are already stabilized on it, and relatively less on diversion and misuse issues at this time
- Enhance social distancing at the OST clinic by mechanical segregation and improvising the patient access to service area
- Maintain the service for already existing patients
- Enhance the duration of take-home doses
- Minimize service requirements
- Enhanced social distancing at the OST clinic by

INTERIM STANDARD OPERATING PROCEDURES AS BEING CURRENTLY PRACTICED IN DRUG DE-ADDICTION AND TREATMENT CENTRE, POSTGRADUATE INSTITUTE OF MEDICAL EDUCATION AND RESEARCH, CHANDIGARH

Note: Individual institutes, hospitals, and clinics running OST service can adapt these SOPs according to their characteristics, needs, demand, and resources; so long the basic principles as mentioned above are adhered to.

1. OST group counseling on face-to-face basis to be suspended as of now. Meetings may be attempted using online platforms (e.g., Zoom) if feasible
2. Urine testing for drugs to be suspended as of now, other than exceptional cases on strong medical suspicion
3. No new patients to be started on OST induction at this time. Patients in acute need of treatment, for example, overdose, acute withdrawal, should present in emergency medical OPD, briefly assessed, and depending on assessment may be either provided with a short-term provision of BNX for withdrawal management, or admitted to de-addiction indoor facility for proper OST induction
4. For stable/maintained patients attending the OST clinic, medicines will be dispensed but case record files will not be taken out of the reception area
5. The patients will be allowed to enter the (a) outer hall, (b) reception/registration area, and (c) treatment area by batches of 5 each, controlled by personnel at each entry point
6. Everyone (including staff) will be asked to maintain a distance of about 6 feet from one another
7. The registration clerk will register the patients on the hospital information system as usual, but will also note down the mobile number of each patient so that later a tele-group meeting may be arranged by distance meeting software like Zoom
8. After entering the treatment area, nursing staff will carry out screening for COVID-19 by asking about the presence of symptoms, having a close contact with the disease or with symptoms suggestive of COVID-19, and international travel history in the past 1 month. If any of these is positive, the patient (after the doctor’s consultation) will be referred to the emergency for further assessment of “suspected” COVID-19
9. Following the screening, the patients will be briefly seen by the duty doctor (Senior Resident) who will write prescription for 2 weeks (instead of the usual 1 week), specifying the exact number of tablets of BNX dispensed
10. After this, the pharmacist on duty will dispense the tablets. He/she will sign the medication-receipt register on the patient’s behalf
11. The patient will immediately exit after collecting the medicine, and the cycle will continue
12. At no point in time will there be more than five patients in any given area. The personnel at the various entry points will coordinate the flow of entry and exit of the patients
13. Alcohol-based hand sanitizers will be kept at the point between outer hall and reception area for use by the patients. Another one will be with the registration clerk and a third one in the treatment area
14. For patients attending unscheduled or out-of-turn, they will be provided BNX till their next scheduled visit on Tuesday/Wednesday, maximum up to 2 weeks supply
15. For those patients earlier on OST but now missed their medications up to 4 weeks, or one or two scheduled OST attendance (depending on the stage of treatment), they will be provided BNX at their usual maintenance dose
16. However, those patients earlier on OST but now missed their medications beyond 4 weeks will require fresh induction on OST with the usual protocol
17. As of now, there will be no provision of home delivery of BNX for isolated/quarantined patients
18. Patients having difficulty of access to our OST service due to travel restrictions will be encouraged to access local OST services such as those for injecting drug users (IDUs) operated under the National AIDS Control Organization (NACO), other government or private OST facilities, Outpatient Opioid-Assisted Treatment Clinics (Punjab), or Drug Treatment Clinics (DTC) operated under the DTC Scheme of the National Drug Dependence Treatment Centre (NDDTC), All India Institute of Medical Sciences (AIIMS), Delhi
19. Arrangements will be made to procure and stock sufficient supply of BNX as per anticipated requirement, ahead of time
20. A message has been put up at PGIMER website that OST services for already registered patients will continue
in PGI but no new patients can be seen till the OPD is closed

21. Those presenting at Emergency Medical OPD with acute substance-related complications (including acute withdrawal or toxicity) will be reviewed by the Consultation-Liaison Team of the Department.

OPERATIONAL ASPECTS

Structural aspects for enhancing safety of patients and staff

The OST clinic area has been divided into three sections – waiting area, registration area, and consultation area. There are two glass doors separating these three areas. A maximum of 10 patients (preferably five) are allowed in the waiting area at any time, and five in each of the other two areas. A minimum physical distancing of 5–6 feet is ensured between patients and staff. All patients enter the registration premises after self-hand sanitization and take a seat. He/she does not have to stand in the queue and is called by the registration clerk on completion of one registration. A registered patient can enter in the consultation area if the consultation area has less than five patients.

In the consultation area, there are three consultation rooms. The COVID-19 screening by a trained nursing staff takes place in the first room. If the screening is positive, it is marked and the patient then sees the doctor. The doctor, in addition to prescribing BNX, refers the patient to the emergency COVID-19 desk (situated in a different building). Finally, the patient would take medication from the pharmacist and leave the clinic after self-hand sanitization.

Functional aspects for enhancing flexibility of operation

Schedule of the clinic

The standard OST clinic for patients in the stabilization or maintenance phase runs twice a week in the afternoons. However, during the time of COVID-19 outbreak, the clinic was kept open for all working days, throughout the entire working hours (8:30 AM–5 PM). We are thus able to accommodate maximum number of patients, to avoid episodic gathering of patients, to minimize exposure both for the patients and health-care professionals (HCPs).

Duration of the take-home-dosage

All patients, irrespective of the phase of treatment (stabilization or maintenance), are given take-home medications for 2 weeks.

Dispensing medication to a “reliable” third-party

Patients’ relatives, friends, and acquaintances are allowed to pick-up the take-home dosage of the patients. To ascertain reliability, patients are contacted on telephone, and the following points are clarified: the third party should be patient-designated; he/she will make sure that the medication will be delivered to the patient as early as possible.

Public health aspects for enhancing response to COVID-19 outbreak

Information dissemination

We believe that contact with the HCP during the OST clinic visit is an opportunistic setting to educate patients about the risks, prevention, and management about the COVID-19. All the patients are asked to self-administer a knowledge assessment questionnaire. Colorful posters explaining the mode of transmission, preventive measures, and symptoms are displayed in the waiting and registration areas. In the consultation area, we played the videos released by the government of India. Patients are also encouraged to ask questions to HCPs (nurses and doctors) about any questions on COVID-19.

Minimize exposure and maximize the output

Half of the workforce is working from home without compromising the multi-disciplinary nature of the clinic. However, all group sessions and individual-based sessions are suspended as of now.

All the HCPs are encouraged to wear three-layered surgical masks, single-gloves, and to wash their hand before wearing and after removing the gloves. HCPs practice social-distancing and ensure that the patients maintain the same too. The chairs, desks, and tables and door knobs/handles are cleaned every 2–3 h.

UNMET NEEDS AND CHALLENGES AHEAD

There are a number of unmet needs and challenges ahead, some of which are mentioned below, with tentative suggestions:

• How to ensure regular supply of OST medication, in view of the restrictions on interstate transport of goods? (This is a major problem. The Government of India should declare buprenorphine, BNX and methadone as essential medications [this is also per the WHO List of essential medicines] and allow the transport of such medication, of course, with proper paperwork)

• How to induct new patients with opioid dependence on OST in view of OPD closure, patient and staff safety, mandated need for in-person assessment, and limited health-care workforce? (Tentative suggestion: such patients in acute need of treatment, e.g., overdose, acute withdrawal, should present in emergency medical OPD, briefly assessed, and depending on assessment may be either provided with a short-term provision of BNX for withdrawal management, or admitted to de-addiction indoor facility for OST induction)

• How to reach medication (BNX) to patients already on OST who are currently under quarantine, in prison, admitted elsewhere or self-isolated? (Tentative
sharing our experience and these interim SOPs can help those opioid-dependent patients on OST to continue to receive their medication. It is to be reiterated these are the SOPs being practiced in our center as of now. Individual institutes, hospitals, and clinics running OST service can either follow or modify these SOPs according to their characteristics, needs, demand, and resources; so long, the basic principles as mentioned above are adhered to.

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