Poor availability of opioid medications for treatment of opioid dependence in India: A persistent pain in the neck

Atul Ambekar, MD
Professor
National Drug Dependence Treatment Centre (NDDTC), All India Institute of Medical Sciences (AIIMS), New Delhi
atul.ambekar@gmail.com

Indians have been using opium for many centuries, as a recreational substance as well as a household medicine. Indeed, India is one of the largest producers of raw opium for medicinal purposes. In addition the unique geographical location of India – nestled between the high illicit opium producing regions (the 'golden triangle' and the 'golden crescent') – means that it is not surprising to find a high prevalence of illicit opioid use in India.

However, despite having a sizable number of people who use opioid drugs and people who inject drugs (almost all of who suffer from opioid dependence), India suffers from a poor availability of opioid agonist medications for the treatment of opioid dependence.

Opioid Agonist Treatment (OAT) previously known Opioid Substitution Treatment (OST) is the most recognized and evidence-based treatment for opioid dependence. Even the Indian treatment guidelines, recommend OAT as the most preferred option for long-term pharmacological treatment. Yet the availability of this modality of treatment has remained pathetically low in India.

OST in India: A brief history

Interestingly, long before the world recognized the properties of methadone as a maintenance agent for heroin addiction, India had the much regulated system of 'opium registry'. Under this system, recognized and people who were registered dependent on opium were supplied opium through licensed outlets for their personal consumption, periodically (something akin to the modern day OAT). Sadly, this system has been allowed to die a natural death.

The modern version of OAT (TECHNICALLY DON'T KNOW HOW TO CHANGE OST TO OAT IN THIS LINK)began in India, as early as in late 1980s, when some health-care providers began prescribing and dispensing low-dose sublingual buprenorphine tablets (available as analgesics) to patients with heroin dependence. By early 2000 the standard dose formulation of buprenorphine (2mg) was available, and by 2005-06, the fixed dose combination of buprenorphine-naloxone was available in India (approved specifically for the treatment of opioid dependence, by the Indian drug control authorities). Yet another

important milestone was incorporation of OAT as a strategy in National AIDS Control Program, whereby OAT centres (located in NGOs or Government Hospitals) started dispensing buprenorphine tablets, as daily observed treatment to people who inject drugs (PWID), as a HIV-prevention strategy. In the year 2012, Methadone was made available in India and as a pilot project, its effectiveness and feasibility was successfully demonstrated.

At a very slow pace, OAT in India continued to grow, though the coverage never reached anywhere near adequacy. The cost of medications – both buprenorphine and methadone – in India is a fraction of their costs in the International market. Thus, the resource crunch expected in a developing country like India, is not the principal reason behind the lower availability of these medications.

OAT in India: the policy landscape

Indian drug law, the Narcotic Drugs and Psychotropic Substances Act (1985), rightly recognizes that drug misuse must be curbed and yet the narcotic and psychotropic drugs should be available for medical and scientific purpose. In addition to this law, the pharmaceutical preparations, are also governed by the Drugs and Cosmetic Act (1940). Additionally, we have a National Policy on Narcotic Drugs and Psychotropic Substances (2012), which unfortunately makes some very disparaging remarks about OAT, for which it has been criticized, by the scientific community. It is the lack of clarity regarding the scopes and purposes of these laws and their implementation that is at the heart of poor availability of buprenorphine and methadone as OAT in India.

Under the Indian law, buprenorphine has been categorized as a psychotropic. However, a specific rider has been attached by the drug controller authorities to the sublingual buprenorphine tablets. These tablets are meant to be supplied only to the Government authorized "De-Addiction Centres". Unfortunately, the phrase 'de-addiction centre' has not been clearly defined anywhere. As a result, physicians who operate clinics for the treatment of opioid dependence, find it extremely difficult to provide OAT to their patients using buprenorphine or buprenorphine-naloxone tablets. Those few, who dare to do so, are often apprehended by the law. In the year 2014, two psychiatrists were arrested and put behind bars on the charges of 'illegally' stocking buprenorphine tablets. As a result, the fear-stricken psychiatric community almost stopped providing buprenorphine treatment and the patients were forced to resort to using illicit heroin again. This was clearly demonstrated in a recent epidemiological survey, in which less than 10% of people who are opioid dependent in the state of Punjab, reported having had access to medical treatment for opioid dependence 'ever'. Clearly, the existing policy framework has succeeded in restricting doctors from providing, and thus limiting the patients from accessing this most evidence-based treatment.

The policy scenario for methadone on the other hand is emerging as much more favorable. Despite being a pure agonist and classified as a narcotic in the International regulatory framework, methadone has been accorded the status of 'Essential Narcotic Drug' through a recent amendment to the NDPS Act. This welcome move, essentially paves the way for wider and easier availability of methadone in India, even at the level of primary health care. Actual implementation of this legal reform is however, yet to be seen.

Impact of restrictive policies on access to treatment

This regulatory quagmire has resulted in very few health care providers, using buprenorphine or methadone for treatment of opioid dependence. A vicious cycle has been set in: few teaching institutes using OAT, resulting in very few trainees getting an exposure to OAT leading to very few service providers with capacity to provide OAT. Ultimately, it is the patients with opioid dependence who are forced to live a life of addiction having no access to the evidence-based, safe and effective treatment. A large number of research reports and reviews have commented upon poor coverage of OAT in India. Just about 10% of people who inject drugs have access to OAT in India. Among people who don't injecting opioids (estimated to be about 2 million as per a 2004 National Survey), the figures for coverage would be even poorer.

Healthier Drug Policies in India: recommendations

A conducive policy environment needs to be created in which the health providers, can fearlessly prescribe and dispense OAT to their patients and the patients with opioid dependence have access to the most effective option for leading an addiction-free, productive life. First and foremost it is essential to bring a *clarity to the legal status of buprenorphine in India*, facilitating easier access to buprenorphine tablets. Additionally, there is a need to *build the capacities of health-care providers* to address the opiophobia, displayed by some of them. Finally, the *law-enforcers need to be oriented and educated* to enable them distinguish a drug dealer from a health-professional providing a scientific and legally-valid treatment to her patients.