Workshop on developing Standard Operating Procedure for Psychiatrists for using Controlled Medications (Narcotic Drugs and Psychotropic Substances)

PROCEEDINGS

Date: 29th April 2024, Monday

Venue: Conference Hall, National Drug Dependence Treatment Centre, AIIMS, Kamla Nehru Nagar, Ghaziabad

Organized by: NDDTC, AIIMS, New Delhi and Addiction Psychiatry Society of India (APSI)

Purpose:

1. To discuss the proposal to develop Standard Operating Procedures (SOPs) for Psychiatrists for using Controlled Medications (Narcotic Drugs and Psychotropic Substances).
2. To discuss the proposal to identify and list the rules and regulatory provisions pertaining to using Controlled Medications (Narcotic Drugs and Psychotropic Substances) by psychiatrists.

Participants (list annexed):

NDDTC, AIIMS: Dr Rakesh Lal, Dr Anju Dhawan, Dr.Sonali Jhanjee, Dr Atul Ambekar, Dr Ravindra Rao, Dr Roshan Bhad

Representatives of Professional Societies:

AOP: Dr. Rupinder Kapoor, Dr. Ashish Sharma

APSI: Dr. Ashwin Mohan

IASP: Dr. Abdul Majid

IPS: Dr. Sujit Sarkhel, Dr. Aleem Siddiqui

IAPP: (sent regrets)

Law Enforcement Agencies:

Central Bureau of Narcotics: Shri Dinesh Bouddh, Shri Brijendra Choudhury, Shri Siddharth, Shri Aditya Ranjan, Shri Parveen Dhol, Shri Gaurav Sharma

Narcotics Control Bureau - Shri Shailesh Jambotkar

Central Drugs Standard Control Organisation- Dr. Santosh Indraksha

Inaugural session

The inaugural session of the workshop began with the welcome address by the chief, NDDTC Prof Rakesh Lal and introduction of all the participants. This was followed by a brief address by Prof Atul Ambekar in which he explained the background of the workshop and walked the participants through the agenda. Prof Ambekar highlighted that the prevalence of substance use and substance use disorder (SUDs) is high in India and there exists more than 80% treatment gap in availing treatment. While there has been an effort by the government to mitigate the gap in recent years, it remains wide. Hence the private sector needs to continue to provide treatment to a substantial proportion of patients with SUDs. Pharmacological treatment is known to be the mainstay of treatment SUDs. Many medications which are effective in the treatment of SUDs are themselves scheduled as narcotic and psychotropic and hence are stringently regulated. Many psychiatrists face challenges while procuring, stocking and dispensing these medications. There appears to be a serious degree of mistrust between the Law Enforcement Agencies and the Doctors. Hence, there has been a

felt need among the doctors that there should be a set of standard set of operating procedures for procuring, stocking and dispensing the controlled medicines. In addition, if there are some rules and regulations which need to be amended, those need to be identified. Prof Ambekar thanked the representatives of the professional societies of psychiatrists and especially to the law enforcement officers for joining the workshop and implored the participants to utilize the opportunity effectively, in the best interests of patients as well as healthcare providers.

Session 1

In the first session, two powerpoint presentations were made to set the context of the workshop.

1. **Overview of laws and regulation relevant for psychiatrists for using controlled medications – Dr. Ashwin Mohan**

Overall, the presentation by Dr Mohan was about:

A. Need for awareness regarding the laws and regulations pertaining to the medications which are used for treatment especially about their procurement, stocking, transport, dispensing and disposal
B. Details of various sections under these acts
C. Challenges being faced by doctors while implementing them
D. Issues with record keeping and documentation

Highlights of the presentation by Dr. Ashwin Mohan:

- The assumption that an addiction treatment center / de-addiction center has to be an inpatient facility is incorrect since the majority of the patients are treated on an outpatient basis.
- The NDPS Act appears to be skewed towards enforcement rather than achieving a balance between preventing diversion and ensuring availability.

- The Act does not differentiate between illicit drug traffickers and the licit entities (physicians, chemist, wholesalers, manufacturers, C & F agents etc.). Moreover, the licit entities always deal with the commercial quantities and hence any alleged contravention attracts severe penal measures.
- The matters get further complicated since many state Governments have implemented 'state deaddiction rules' where different standards are applicable.
- The Drugs and Cosmetic Rules, 1945 empower a registered medical practitioner (RMP) to procure, stock and dispense medications (including those scheduled as narcotic or psychotropic) to their own patients.
- There remains a lack of clarity about the term "dosage units" considering the wide variety of drug delivery systems (capsule, tablet, liquid, patches, sublingual etc).
- Despite doctors being authorized to procure, stock, and dispense medications, RMPs are still booked for illegal possession. It may be noted that there is no requirement of licenses for RMPs in D&C Act and Rules for use of these medications.
- Rules appear to be unclear about the dispensing method. (Same person or different persons? Same room or different room? Pharmacy license? Bills or receipts?)
- The law enforcement agencies often disregard the therapeutic aspects of controlled medications and tend to act as if every patient seeking treatment wants to only 'abuse' and divert the medications.

In the Q&A session, this particular issue was clarified by all the representatives of professional societies that only a small minority of the patients divert the medications. Moreover, the diverted medications are usually used by the other patients who cannot come to the health care center for some reasons, to manage their withdrawals (effectively as self-treatment). Strategies to minimize the diversion include involving the patients' family members to supervise the medication; frequent urine drug screening, dispensing only for limited duration etc.

Clarification was sought by law enforcement officers specifically about the average dose of buprenorphine for treatment of opioid dependence. It was clarified that dose requirements

depend on many factors and there may be substantial difference between dose requirements of different patients as well as for the same patient in during different life situations. Thus, the dose prescribed to a patient cannot be (and hence has not been) defined in the law.

2. Doctors in trouble with the law: A series of cases - Dr. Ashish Sharma

Dr Ashish Sharma presented a series of real cases where doctors were booked under the NDPS Act and the allegations mentioned by enforcement agencies. For each of the cases he presented briefly the profile of the doctor booked, the nature of allegations, and subsequent legal proceedings.

Some of the cases presented and discussed include:

1. A qualified psychiatrist consulting patients in his own clinic was allegedly booked under illegal possession of psychotropic drug, since there was no license to stock and sale of psychotropic drug, mismatch in dispensing records (hence diversion)

2. A MBBS doctor dispensing benzodiazepines to his own patients in his clinic was booked under contravention of state De-addiction center rules, on the allegation of stocking and sale of "prohibited" medicines from his clinic and thus booked under NDPS act.

3. A psychiatrist owning a hospital registered under MHCA 2017 consulting patients in his hospital was allegedly arrested with illegal possession of multiple medications.

4. A psychiatrist owning a hospital registered under MHCA 2017, awaiting renewal of state deaddiction centre permission was accused of running a deaddiction centre, storing and dispensing "prohibited drugs" without a valid license. The law enforcement agencies while raiding the premises accessed the patient register, contacted them telephonically and since patients (out of fear of legal repercussions) denied being 'addicts', arrested the doctor.

5. Notices were sent to hundreds of psychiatry clinics in Rajasthan to submit all sale, purchase and dispensing records pertaining to controlled medicines.

During the discussion it was highlighted that the cases presented here represent only the tip of the iceberg while many other doctors have also experienced enquiry through phone by authorities which in itself is a distressing experience. The number of psychiatrists behind bars is steadily increasing. Notably, the house was informed of the birth of a "De-Addiction Mafia", i.e. de-addiction centers being run by influential and wealthy businessmen without any medical qualification, who employ psychiatrists to run their centers. As a result, many of the qualified and experienced psychiatrists have stopped treating patients of substance use disorder since they are living a life of constant fear of prosecution. This in turn has resulted in inaccessibility to proper treatment and thus pushing them to seek medicines from illicit sources or restarting illicit drugs, thereby ironically strengthening the illegal drug market.

Session 2

In the next session, all the participants were requested for their brief remarks and reflections.

AOP: Dr. Rupinder Kapur mentioned the chronic relapsing course of substance use disorder which has a biological basis. He also highlighted the barriers in dispensing buprenorphine to patients with opioid use disorder. Despite the best intentions psychiatrists fear to prescribe and dispense these medications. This creates a huge disservice to the patients. He suggested that before a doctor gets booked under the NDPS Act, a committee of medical professionals along with law enforcement agencies should first evaluate the merits of the case and the need for further legal proceedings. He emphasized the need to clearly distinguish between licit entities and illicit traffickers.

IASP: Dr. Abdul Majid emphasized the need to have more outpatient and community-based treatment services (as opposed to inpatient 'deaddiction centers'). He also shared his

observation on the change in the pattern of substance use among the Indian patient population: from cannabis till a few decades ago to heroin and other opioids in the current era. He requested the law enforcement agencies to provide an facilitating environment to the practicing psychiatrists enabling them to provide the best possible service to their patients.

IPS: Dr. Sujith Sarkhel appealed for protection of the interests of clinicians and appealed to the law enforcement agencies to avoid hurriedly jumping to conclusion. He agreed with the basic objective of the workshop to develop a proper Standard Operating Procedure (SOP) which can be followed by the clinicians to minimize the risk of breaking the law, even if inadvertently.

IPS: Dr. Mohammad Aleem Siddiqui pointed out the "welfare of the public" to be the primary aim of the workshop along with preserving and protecting the qualified clinicians. He expressed his concerns that the pathway to the illegal market would increase if there is a roadblock to the clinicians in prescribing essential treatment. Law enforcement officers should avoid interpreting clinical guidelines since it is beyond their mandate and expertise (for instance, the dose requirement is subjected to human variation and genetic diversity). He also emphasized that young doctors should be made aware about the common traps of private "De-addiction centers". He suggested that the penalty for the first contravention should be lenient and the lacunae should be pointed out clearly instead of more rigorous punishment.

CDSCO: Dr. Santosh Indraksha, briefly discussed the relevant provisions of D&C Act, 1940 and Rules thereunder. He highlighted the fact that even if the law appears to be old (1940) it keeps with the changing times through various amendments to the Act and rules which are notified from time to time. He emphasized that a RMP can stock and dispense a medication under the provisions of exemptions provided in Schedule-K of the Drugs Rules for his/her patients but such medicines cannot be sold (i.e. an invoice of the drug cannot be raised). He also listed some of the typical violations which have been found during inspection by the drug control officers:

1. Non availability of the purchase records
2. Possession of excess quantity of medicines disproportionate to the patient handled.
3. Sale of drugs with invoices (in the absence of a valid sale license)
4. Improper storage of drugs
5. Drugs labeled as hospital supplies, found being sold by RMPs.
6. RMP found to be involved in import/manufacture/sale & distribution of the drugs
7. Keeping an open shop (unlicensed)
8. Non maintenance of records for dispensing of these drugs as specified under Schedule K or X
9. Not allowing Inspector to inspect, or to take samples for testing.
10. Dispensing of the drug in the absence of the competent person as per Schedule K.

He further informed the house that such typical violation have penal provisions under Section 27 (d), and the penalties have recently been amended through Jan Vishwas Act, 2023 wherein the fines have increased by many folds (5lakhs) and imprisonment is omitted. However repeat offenders have to deal with stricter legal actions.

At the end of his presentation, he has listed the expectations from the RMPs listed below-

1. Maintenance of Purchase records and bills, including distribution records
2. Labeling of the Scheduled drugs as per the requirements of the Schedule K.
3. Maintenance of registers/ records for the dispensing of the drugs
4. Drugs shall not be sold.
5. Quantity of drugs stored commensurate to the patients being handled by the RMP.
6. Non-involvement in the import/manufacture/sale-distribution of the drug.
7. Not keeping an open shop.
8. Maintenance of the storage condition.
9. Drugs labeled to be sold to hospitals/ institutional supplies shall not be found in possession of RMPs.
10. Shall not dispense/sale expired drugs.
11. Retention of the record for the specified period.

12. Dispensing of the drug by the institute in the presence of the competent person as per Schedule K

The house shared their observation that minor violations in Drugs and Cosmetics Act are automatically booked under NDPS Act. This is a grave problem since under the NDPS Act, a person is presumed guilty until proven innocent.

NCB: Shri Shailesh Jambotkar, walked the house through the brief history of the NDPS Act and informed that the Act came at a time when the 'war on drugs' was at its peak. Ever since its inception, various amendments had come with the intention to control and regulate the narcotic drugs and psychotropic substances. He acknowledged that the Government is working on future amendments to the Act. He expressed the problem in distinguishing licit and illicit entities under the NDPS Act.

CBN: Shri Dinesh Boudh agreed with the remarks of the previous speakers and reported that efforts have been going on for amendments to the rules. In the draft of the NDPS amendment bill, a provision for leniency for minor violations has been incorporated. He also cited case examples whereby the doctor's prescriptions were forged and hence emphasized the need of proper documentation. He reiterated that accountability and record keeping is an essential demand from Law Enforcement Agencies. He agreed that there appears to be a lack of understanding between Doctors and Law Enforcement Agencies. To address this, he suggested frequent interactions and involvement in capacity building / professional development programs by doctors for law enforcement officers and vice versa.

In general, all the participants welcomed the idea of development of SOPs and need of amendment of regulations. They also expressed their commitment to support this initiative.

Session 5

Discussion on developing SOPs: structure, process, timelines

In this session the house discussed the process of development of SOPs. Following decisions were arrived at:

- There was consensus on development of a SOP document which will include inputs from all the professional societies invited to the workshop.
- The draft SOP document will also be shared with the representatives from the Law Enforcement Agencies present in the workshop for their inputs and will be finalized after a consultation with them.
- To clarify further, the representatives of NDDTC AIIMS and the professional societies participating in the workshop will be credited as the authors of the SOP document, while the law enforcement officers will be acknowledged as experts who provided their inputs during the consultation.
- The pre-final draft of the SOP will also be sent to the Drug Consultative Committee of the CDSCO. MOH&FW for its deliberations and further recommendations, as DCC deals with uniform administration of the provisions of the D&C Act, and Rules thereunder. This would also help disseminate the information/SOP to all State/UT Drugs Controllers, who are the ultimate authorities to verify the applicable compliances.
- Likely structure of the SOP document:
    - *Objectives and scope*: The document needs to clearly spell out the objectives, the scope, the target audience (who it is meant for) etc.
    - *Responsibilities of entities and individuals*: The document must specify the obligations and responsibilities expected of the entities (organizations or establishments such as a hospital, nursing home, clinic etc.) and the individuals involved (proprietor, doctor, nurse, pharmacist etc.)
    - *Description of the processes*: Do's and Don'ts for all the steps involved such as procurement, receipt, storage and safekeeping, prescription, dispensing, monitoring etc.
    - *Training / orientation / professional development*: The document can provide recommendations about regular orientation to healthcare professionals on the issues concerning regulation of controlled medications.

- In general, the SOPs should leave little room for law enforcement agencies to misinterpret and should be easily implementable by the doctors.
- It was also noted that the existence of such a document will not provide a complete solution to the current problem which the clinicians are facing - many of which arise due to presence of undesirable elements within the community of healthcare providers as well as among the law enforcement officers. However, such SOPs will help to delineate or isolate such 'black sheep', existing in the system.
- The house agreed to form a sub-committee for developing the first draft of the SOP. The sub-committee on drafting the SOP will include:
    - Dr. Ashwin Mohan
    - Dr. Rupinder Kapoor
    - Dr. Aleem Siddiqui
    - Dr. Abdul Majid

NDDTC and APSI secretariat will be involved in working closely with the sub-committee.

Discussion on identifying rules in need of amendment:

The house also discussed the need to identify and list the existing rules and regulations in the NDPS rules / D&C rules / any state specific rules which need to be amended since they hinder effective provision of mental healthcare services.

- The outcome document of this process should provide: (a) rules which need to be amended, (b) justification / remarks for the same and (c) proposed amendment.
- The document may also provide recommendations for advocacy for amendment.
- A sub-committee of the following members will look into this and prepare such a list:
    - Dr. Ravindra Rao
    - Dr. Ashish Sharma
    - Dr. Sujit Sarkhel
    - Dr. Abdul Majid

NDDTC and APSI secretariat will be involved in working closely with the sub-committee.

Next steps:

- The house decided that by 31st May 2024 both the committees will share their drafts.
- The drafts of both the documents will be shared with the law enforcement agencies represented here.
- A consultation workshop will be organized within 2-3 weeks of circulation of the first draft to finalize both the documents.
- The documents will be released in public domain jointly by all the professional societies involved.
- Since, IAPP representatives (Dr. Rajesh Nagpal and Dr. Sunil Mittal) could not join the consultation workshop, they will be offered to join the drafting committee and upon their acceptance and inputs IAPP will also be one of the stakeholders / 'owners' of the SOP document.

The meeting adjourned with a sense of determination and purpose. Dr Atul Ambekar thanked the house for their participation and active inputs.

Annexure 1: List of Participants

S.No	Name	Organization	Designation	Contact number	Email Id
1	Dr. Abdul Majid	IASP	Representative	9018111157	maajid72@gmail.com
2	Aditya Ranjan	CBN	Superintendent	8989475864	aditya.ranjan@gov.in
3	Dr. Aleem Siddiqui	IPS	Treasurer (representative)	7607358897	docaleem@gmail.com
4	Dr. Anju Dhawan	NDDTC, AIIMS	Professor	9818329539	dranjudhawan@gmail.com
5	Dr. Ashish Sharma	AOP	Secretary (representative)	9915598282	dr.ashish.s@gmail.com
6	Dr. Ashwin Mohan	Euzen Mental Health Clinic, Chandigarh	EC member (representative)	9814301303	ashwinpsycho@gmail.com
7	Dr. Atul Ambekar	NDDTC, AIIMS	Professor	9811155682	atul.ambekar@gmail.com
8	Shri Brijendra Chowdhary	CBN	Deputy Commissioner	9161826181	Brijendra.chowdhary@gov.in
9	Shri Dinesh Bouddh	CBN	Narcotics Commissioner	9336922101	bouddh.dinesh@gov.in
10	Dr. Rakesh Lal	NDDTC, AIIMS	Professor & Chief	9811381983	drrakeshlall@gmail.com
11	Dr. Ravindra Rao	NDDTC, AIIMS	Professor	9810323164	dr.rvrao@gmail.com
12	Dr. Roshan Bhad	NDDTC, AIIMS	Additional Professor	9717756119	drroshansindia@gmail.com
13	Dr. Rupinder Kapur	AOP	President (representative)	9417063799	rupenk123@gmail.com
14	Dr. Santosh Indraksha	CDSCO	Deputy Drug Controller	9820118750	Santosh.indraksha.cdsco@nic.in
15	Shri Shailesh Jambotkar	NCB	Additional Director	8879160001	Sd.jambotkar@gov.in
16	Dr. Sonali Jhanjee	NDDTC, AIIMS	Professor	9818621709	Sonalijhanjee@gmail.com
17	Dr. Sujit Sarkhel	IPS	Editor (representative)	9836074700	sujitsarkhel@gmail.com
18	Shri. Parveen Dhull	CBN	Inspector	9999151105	dhull829@gmail.com
19	Shri Gaurav Sharma	CBN	Inspector	8178652136	gauravsharma1728@gmail.com
20	Shri Sidharth Sahai Malhotra	CDSCO	Assistant Drug Controller	9501999795	sidharth.cdsco@nic.in

Annexure 2: Agenda

Time	Activity	By…
10:00 – 10:30	**Registration**	**NDDTC and APSI**
10:30 – 11:00	Welcome Remarks Introduction to the agenda and introduction of participants	Prof. Rakesh Lal, Chief, NDDTC Prof. Atul Ambekar, NDDTC
11:00 – 11:20	An overview of laws and regulation relevant for Psychiatrists for using controlled medications	Dr. Ashwin Mohan, Chandigarh
11:20 – 11:40	Doctors in trouble with the law: A series of cases	Dr. Ashish Sharma, Chandigarh
11:40 – 11:50	Remarks and reflections	Dr. Santosh Indraksha, CDSCO
11:50 – 12:00	Remarks and reflections	Shri Shailesh Jambotkar, NCB
12:00 – 12:10	Remarks and reflections	Shri Dinesh Boudh, CBN
12:10 – 12:30	Remarks by the representatives of Professional societies (5 minutes each) • AOP • IAPP • IPS	Moderated by Atul Ambekar
12:30 – 13:00	Open discussion	Moderated by Ravindra Rao
13:00 – 14:00	Discussion on developing SOPs: Structure, process, timelines	Moderated by Ashwin Mohan
14:00 – 14:30	**Lunch**	
14:30 – 15:30	Discussion on identifying and listing rules and regulations in need of amendments	Moderated by Ravindra Rao
15:30 – 16:00	Concluding / Valedictory session	Prof. Anju Dhawan, NDDTC