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## Access to controlled medicines for palliative care in India: gains and challenges

### SUNITA VS BANDEWAR

*"It is critical to provide attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity."*

—UN Committee on Economic, Social and Cultural Rights

*"The failure to ensure access to controlled medications for pain and suffering threatens the fundamental rights to health and to protection against cruel, inhuman and degrading treatment."*

—UN Special Rapporteurs on Health and Torture

### Abstract

*It was in the early 1990s that an appeal was made, both in India and globally, for access to palliative care to be treated as a human rights issue. Over the past few years, India has witnessed robust advocacy efforts which push for the consideration of palliative care and pain management as a human right. Central to this*

*paper is India's Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985: its genesis, its critique, and the amendments aimed at enhancing access to the NDPS for medical care and research. I refer to the advocacy efforts in India, particularly the most recent ones, which led to the amendments to the NDPS Act, 1985 in February 2014; and the contribution of the global and local human rights discourse on palliative care to these efforts. This I situate in the overall status of palliative care in India. Towards the end, I briefly set out the agenda that should be pursued in the coming years to enhance access to controlled medicines for pain management and palliative care.*

### Introduction

In the early 1990s, an appeal was made, both in India and globally (1), that access to palliative care (PC) must be treated as a human rights issue. Among other things, access to controlled medicines, that is, narcotic drugs and psychotropic substances (NDPS), remains central to the realisation of the human right to PC. Access to NDPS is often regulated and controlled around the world, including India, to contain their (ab)use for non-medical and harmful purposes. Over the past few years, India has witnessed robust advocacy efforts aimed at changing the situation and ensuring that PC and pain management are recognised as a human right.

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However, despite local and global efforts to improve patients' access to PC, such care continues to be out of the reach of the millions in need in India. This warrants further strengthening of the efforts towards improving the situation. Many more must be drawn into the ongoing advocacy efforts, services need to be provided and research initiatives taken.

### Concept of palliative care

The World Health Organisation (WHO) defined PC for the first time in 1986 and later revised its definition in 2002 (2). The first definition described PC as "...an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual"(3). The revised definition was more inclusive. It went beyond pain relief and end-of-life (EoL) care to stress the relevance of PC and pain management to patients not responsive to curative care (4). It also highlighted the need for initiating PC earlier in the treatment of the disease. This expanded notion of PC led to a growing movement that encouraged physicians to look upon PC in a wider sense, with attentiveness to psychosocial and existential, or spiritual, suffering (5).

As a result of the WHO's revised definition, specialists in PC, even in the developing countries, have extended PC beyond incurable disease (6). It is no longer restricted to EoL care (7) and in some countries, such as Japan, PC is being integrated into mainstream treatment (8). Likewise, in India, there are many advocating for an integrated PC programme, which provides PC alongside treatment for the relevant health condition (9). Some even speak of the need to recognise the role of PC in promoting cohesion in the community and personal resilience (10). Overall, this shift reflects the breadth of the concept of PC. It underscores the point that access to NDPS is of significance in a wider range of health conditions, throughout the treatment cycle.

### Access to palliative care and pain management in India: an unmet need and inequity

Often, the need for PC is associated with cancer. However, with the increasing incidence of life-limiting illnesses, including not only non-communicable but also communicable ones, the need for quality PC and pain management would only be rising. India has yet to enhance its large population's chances of a pain-free or pain-controlled life when they have a severe, pain-inflicting illness, and enable those with terminal illnesses to pass away in a pain-controlled, dignified manner.

It is estimated that the number of patients requiring PC in India is 10 million, one million of whom have cancer and seven million, other life-limiting conditions (11). It is also estimated that more than one million of the new cases requiring PC every year are cases of advanced cancer (12).

More than half of India's regional cancer centres, which see tens of thousands of cancer patients every year, do not offer

adequate treatment for pain as they do not have morphine or doctors trained for the purpose. It is noteworthy that about 70% or more of the patients at these centres have advanced cancer and are likely to require pain treatment (13). According to a Human Rights Council report, "In 2008, India used an amount of morphine that was sufficient to adequately treat during that year only about 40,000 patients suffering from moderate to severe pain due to advanced cancer, about 4% of those requiring it." (13). Yet another study reported that only 0.4% of patients have access to oral morphine (14). This demonstrates the scale of the unmet need for PC as the use of oral morphine, one of the mainstay therapies for PC and pain management, is considered a proxy indicator of the availability of PC. Also, in 2010, India was ranked the lowest in an assessment of the quality of death (QoD), which covered 40 countries from around the world (15). The QoD index was aimed at measuring the current environment for EoL care, with four constituent sub-indices: Basic EoL Healthcare Environment; Availability of EoL Care; Cost of EoL Care; and Quality of EoL Care. India ranked low (between 36 and 40) on these sub-indices. Also, the distribution of PC facilities in the country is extremely uneven, leading to inequitable access to such care. For example, almost two-thirds of all PC facilities are located in Kerala alone, a state which accounts for only 3% of the total population of India (16). A number of states do not have any PC facilities.

Inequity in access to PC is a global problem as well. Estimates suggest that only about one million persons – a minority – who die each week receive PC. The developing world, which represents 80% of the world's population, accounts for only about 6% of the global consumption of morphine. The Worldwide Palliative Care Alliance (WPCA) estimates that only about 8% of the 100 million people who would benefit from PC, including family members and carers, annually access it (15).

One of the several factors which severely constrain access to PC and pain management is the restrictive regulatory environment for NDPS. Therefore, a law that enables access to NDPS for medical use and research, and putting in place an efficient implementation system are pivotal to ensuring access to controlled medicine.

### Genesis of the NDPS Act, 1985 and its key features

In India, statutory control over narcotic drugs was provided by three legislations – The Opium Act, 1857, The Opium Act, 1878 and The Dangerous Drugs Act, 1930 – until the enactment of the NDPS Act, 1985. However, the statutory provisions of the NDPS became inadequate in the light of the growing trafficking of illicit drugs; the emergence of various new international laws and conventions, such as the UN Single Convention on Narcotic Drugs 1961, the Convention on Psychotropic Substances 1971, and the Convention on Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988; and treaties concerning NDPS. India, being a signatory to these conventions or treaties, was bound to revisit her own NDPS-related legal instruments.

Besides, a number of deficiencies were noted in the laws in India. For example, the scheme of penalties for offences was an inadequate deterrent in the face of the stronger international gangs engaged in drug trafficking. The failure to prescribe a minimum punishment sometimes forced the courts to let off the offenders. Further, no arrangements had been made to address the drug traffickers' increasing use of Indian territory as a site of transit of controlled drugs. There were no provisions allowing officers from various Central enforcement agencies, such as Narcotics Customs and Central Excise, to investigate drug trafficking and abuse offences under the existing laws. In the absence of any comprehensive legal instrument to control the abuse of NDPS, the government was also finding it difficult to address the emergence of addiction to psychotropic substances, such as amphetamines, as opposed to conventional opioids, such as morphine (17).

These factors together necessitated a new statutory instrument, which would appropriately consolidate the three existing Indian laws, and fitting amendments. In response, the NDPS Bill, 1985 was presented to the Lok Sabha on August 23, 1985. It was enforced on November 14, 1985 as the NDPS Act, 1985 (61 of 1985). This Act aims to prevent abuse of NDPS; and prohibit trade in and the cultivation, production, possession, sale, purchase, use and consumption of NDPS, except for medical and scientific purposes under licence.

### **Critique of the NDPS Act, 1985**

The NDPS Act, 1985 was shaped and implemented with the "war on drugs" approach. It failed to acknowledge the principle of balance, that is, it did not succeed in ensuring the availability of NDPS for medical purposes while preventing their abuse. On the substantive front, the Act has many excessively stringent features, such as the denial of safeguards for civil liberties that are normally available within the criminal justice system. Another such feature is the mandatory death penalty for particular repeat offences involving large quantities of drugs. These features make the NDPS Act, 1985, one of the harshest legal instruments in India. The provision of the death penalty has been critiqued on the ground that it infringes the individual's fundamental right to life and liberty as per Article 21 of the Constitution of India. This and the provision of enhanced punishment for offences after previous conviction have also been criticised for their inappropriateness and non-proportionality. For example, drug trafficking is only an economic offence. Therefore, it cannot and should not attract the death penalty which, theoretically speaking, is considered appropriate for those who have committed the offence of taking a human life.

Procedurally, the availability of NDPS for patients in need of pain relief was hampered by the lack of standardised rules across the states. In addition, if a healthcare facility or pharmacy wished to procure, stock and dispense NDPS for medical purposes, it was required to secure 4–5 licences from various ministries/government departments. To make matters worse, acquiring these licences – which were valid for

limited periods – concurrently from the various departments concerned was a painful process, given the slow-paced and inefficient Indian bureaucracy. The stringent licensing requirements, bureaucratic hurdles, excessively harsh and disproportionate penalties, and criminalisation of drug use, combined with the fact that there was little scope for seeking bail and/or for repeals, imposed a restrictive regulatory regime for controlled medicines.

This explains the adverse impact of the NDPS Act of 1985 on the use of controlled drugs for medical and scientific purposes. For example, the data indicate that the medical use of morphine fell by 97% after the enactment of the Act (18). A review by Human Rights Watch (19) of human rights practices around the world between November 2012 and November 2013 stressed the need for reforms in the regulatory environment for drugs. Among other issues, it highlighted the adverse impact of drug control regulations on patients' access to morphine in various countries, including India:

"... in India, Ukraine and Senegal, how cancer patients suffer severe pain due to drug control regulations that render morphine inaccessible; ..." (20: p 32).

The review also says:

"They [Government] should also ensure that anyone with a legitimate medical need for controlled medications like morphine or methadone has adequate access to them." (20: p 40).

The adverse fallout of the NDPS Act, 1985, and reviews such as the one cited above shaped advocacy efforts which led to amendments to the Act.

### **Narcotic Drugs and Psychotropic Substances (Amendments) Act, 2014**

The NDPS Act, 1985 has been amended thrice. The most recent amendments were approved by the President of India on March 7, 2014. The first amendment (1989) made the Act even more stringent, while the second one (2001) partially repaired the damage done by the first. The amendments of 2014, which were ratified on March 7, 2014, were motivated by the need to address the restrictive and stringent regime introduced by the NDPS Act of 1985. They have made the Act more suitable for the needs of healthcare providers and pharmacies with regard to the use of NDPS for medical and scientific purposes. This should help in addressing the need for easier access to controlled drugs for pain management and PC. The recent amendments were driven by civil society, including those deeply involved in the provision of PC as well as patients and their family members.

The specific amendments ratified in 2014 are as follows:

1. A new category of "essential narcotic drugs" [section 2 (viii)] will be created. This will enable the Government of India to notify a list of such drugs that is relevant and feasible for use in medical practice. These drugs will

be subject to the Central Rules [Section 9(1) (a)] and, therefore, will apply uniformly throughout the country. This eliminates the need for the cumbersome practice of securing licences from multiple state departments before the drugs can be efficiently dispensed for beneficial use.

2. The restraints on bail in drug offences will be relaxed.
3. The mandatory death penalty for those previously convicted for certain offences will be revoked.

Central to these amendments is their alignment with the international regulations on drug control. This creates a better balance between drug control and the availability of drugs for beneficial use. It is also hoped that the recent amendments will offer the medical and scientific community more opportunities for research on the drugs to enhance their beneficial use.

### **National-level enabling forces behind NDPS (Amendments) Act, 2014**

The advocacy efforts in India for legal reforms were shaped by the growing recognition worldwide of patients' need to have access to NDPS for pain relief in wide-ranging health conditions at various stages of recovery, as well as that of being terminally ill. Eventually, these efforts gathered momentum and the drug user activists, who were driven by the 'harm reduction' approach, called for amendments to the Act. These activists advocated for treatment for drug dependence, rather than victimisation of drug users. These issues were raised through legal means, such as public interest litigation (PIL).

Advocacy for PC was also carried out by those who were in favour of increasing access to drugs for medical and scientific purposes. This necessitated easing of procedural matters and facilitating the process of securing licences for acquiring, stocking and dispensing NDPS. Through a joint action taken by PC activists in collaboration with others, the rules of the various states were simplified in 1998 as per the instructions of the Department of Revenue. This was only partially beneficial, considering that it took a period of 15 years to simplify the rules in 16 states. A watershed was reached in 2007, when a PIL was filed by the Indian Association of Palliative Care (IAPC) in collaboration with cancer patients in need of adequate access to pain relief, or their families. Subsequently, in June 2012, representations were filed by civil society groups (including Pallium India, the IAPC and Lawyers' Collective) with the Department of Revenue, Ministry of Finance and Standing Committee on Finance with regard to the amendments they considered necessary. This paved the way for the latest amendments.

### **International-level contributors to the NDPS (Amendments) Act, 2014**

The global scenario vis-à-vis access to controlled drugs has witnessed a paradigm shift over the past decade, particularly since 2008. This had a great impact on the push for progressive reforms in the NDPS Act, 1985. The issue of peoples' access to PC gained much-needed visibility when those involved in advocacy efforts were able to draw upon appropriate

UN Conventions and utilise the two mutually reinforcing arguments, "lack of access to palliative care is a human rights concern" and "governments' inability to offer pain relief amounts to torture". The new paradigm also underscored the need to make PC an integral part of the notion of the right to healthcare. As a result of these developments, the need was felt to change the regulatory environment created by the NDPS in a manner that would strike the right balance between "drug abuse" and "drug use for beneficial purposes".

Between 2000 and 2007, at least six important statements or declarations on PC were made in different parts of the world. Each of these explicitly asserted the need for access to palliative care as a human right (21). Most of them emerged in the context of cancer and HIV/AIDS care. They were initiated by professional associations, advocacy groups or non-governmental organisations involved in the care of cancer and HIV/AIDS patients. The growing acceptance, globally, of the argument that access to PC and pain relief is a human rights issue was a response to the increasing misery wrought by the HIV/AIDS epidemic. For example, it was the joint declaration and the statement developed and signed by representatives of numerous international and regional organisations, both from the North and the South, at the XVII International AIDS Conference in Mexico City in 2008 that provided further momentum to the "palliative care as human rights" discourse. Although access to PC was recognised as a human rights issue in India way back in 1994, the global shift gave the advocacy for legal reforms a much-needed fillip and the efforts were expedited in 2011. It is needless to say that India was at the forefront of various advocacy efforts at the global level through several international networks and initiatives, which were focused solely on enhancing people's access to PC and pain treatment. Some of these are the International Association of Hospice and Palliative Care (IAHPC), International Federation of Health and Human Rights Organisations (IFHHRO), Human Rights Watch (HRW), International Psycho-oncology Society (IPOS) and Worldwide Palliative Care Alliance (WPCA). These efforts were aimed at raising the issue at the UN and WHO platform. Articles 5 (recognition of the rights to life, and to freedom from torture and cruel, inhuman or degrading treatment) and 25 (recognition of the right to a standard of living adequate for health and well-being) of the Universal Declaration of Human Rights of 1948, and General Comment 14 of paragraphs 12 and 34 of the UN Committee on Economic, Social and Cultural Rights (22) formed the solid foundation of the argument in favour of integrating PC into the right to healthcare. The Committee stated that parties are "under the obligation to respect the right to heal by, inter alia, refraining from denying or limiting equal access for all persons ... to preventive, curative and palliative health services". It also underscored the importance of enabling chronically and terminally ill persons to die with dignity by attending and caring for them.

Subsequently, a logical and yet more forceful argument drew upon the UN Convention against Torture: "Inability of the governments and healthcare systems to offer palliative care amounts to torture by subjecting individuals to unnecessary

pains or pains that can be alleviated fully or partially". As a result of this, the issue of access to PC and pain treatment found mention in the reports of both Special Rapporteurs on health in the year 2008 (23), and on torture in 2009 and 2013 (24–26). Mendez (25), the Special Rapporteur on Torture since 2010, held that the lack of availability or denial of pain treatment in healthcare settings amounted to torture on three grounds: (i) the severity and extent of suffering warrant the provision of pain treatment to everybody, without any discrimination; (ii) the state is unaware of unnecessary suffering and the fact that no pain treatment is being offered, despite the robust guidance and protocols provided on such treatment by WHO and others; and (iii) the state has no reasonable justification for not providing pain treatment. These developments at the global level lent visibility to the issues related to limited or no access to PC and the scale and severity of the problem.

Not surprisingly, the voices of the affected individuals and their family members played a significant role both in the national and global advocacy for legal reforms in the NDPS Act, 1985.

### **Agenda for enabling and promoting access to palliative care**

Efforts must be made to develop an agenda for research, advocacy and training in the area of pain management and PC. The agenda should be revisited from time to time and pursued across the country in the coming years. The work being done in Kerala is inspiring and could serve as a model for other states of India. While the Indian movement for the "right to healthcare" has come to the forefront and resulted in a few gains, some of the key themes within the "right to healthcare" need to be made explicit in the coming years, one being access to PC. At the same time, as is the case with other themes in health and healthcare, such as women's health and mental health, it is necessary to forcefully push for the necessary reforms in the area of PC, without separating it from the movement for the "right to healthcare". It is also important to undertake activities to create awareness of the newly amended NDPS Act amongst healthcare providers, pharmacists and the people at large; to help them appreciate that access to PC is a human rights issue; and to encourage healthcare providers to be open to integrating PC in their own settings.

There is a need to strengthen empirical research on PC. The research could include situation analysis of the availability of PC. Research also needs to be carried out on knowledge of the NDPS Act among the common people, patients, their families, healthcare providers and pharmacists; the problems faced by these groups in accessing pain treatment, in general, and controlled drugs, in particular, for pain treatment; and the ethical dilemmas faced by healthcare providers on the ground in accessing and providing controlled drugs to their patients. It will be of particular importance to interact with medical doctors and pharmacists to find out if the recent amendments have helped them to get around the problems they feared or actually encountered before the amendments.

Easier access to controlled medicines would rightly be feared now as it might increase the abuse or misuse of these drugs. However, the potential abuse of NDPS could be addressed by setting up systems at the points where NDPS are dispensed, a step which was taken by the PC initiatives in Kerala even before the amendments (27). Other states could learn from and adapt these initiatives. In addition, in the vastly changed overall contemporary context of healthcare provision, systematic research is warranted across India to better appreciate this concern and respond to it accordingly. It would be worthwhile to carry out collaborative research with organisations working with drug users to learn of the impact, if any, of the amended NDPS Act on the patterns and extent of drug use, and increase in drug use. The findings would help to better implement the amended NDPS Act and ensure that the "principle of balance", the key driving force behind the recent amendment, is not breached.

As already mentioned, the models of PC delivery conceived of and implemented in Kerala need to be explored for adoption in other parts of India. Representatives of various constituencies, such as health advocates, healthcare providers, pharmacists and the common people, could be encouraged to help explore and promote this model or variants of the model that would be suitable in different contexts, particularly the interior and remote areas. This is of particular significance in the context of the current rural–urban divide and the nearly nonexistent provision of PC in rural areas. It is possible to create human resources equipped to deliver PC at different levels within the public healthcare system by building upon both the National Rural Health Mission and the National Urban Health Mission. The effective implementation of the NDPS Act (Amendments) 2014 would play a significant role in the coming years.

I hope India can sustain the momentum towards furthering the right to PC and that everyone in need of PC will be able to access it. When in need, everyone, regardless of age, sex, class/purchasing capacity, geographical location, level of awareness regarding PC and pain management, ought to have access to comprehensive and quality PC. Persons braving terminal illness should be allowed to endure their condition in as pain-free a manner as possible and leave this mortal world with the utmost dignity.

**Dedication:** I dedicate this piece to all those who have worked tirelessly to have the NDPS Act amended; to those foot soldiers in Kerala who have translated the concept of community-based palliative care delivery into a reality in response to our severely constrained healthcare scenarios; to those who shaped the palliative care movement in India; and to those who have endured and who continue to brave the pain of life-limiting health conditions.

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## Do medical students require education on issues related to plagiarism?

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**Abstract**

*In the course of our professional experience, we have seen that many medical students plagiarise. We hypothesised that they*

*do so out of ignorance and that they require formal education on the subject. With this objective in mind, we conducted a teaching session on issues related to plagiarism. As a part of this, we administered a quiz to assess their baseline knowledge on plagiarism and a questionnaire to determine their attitudes towards it. We followed this up with an interactive teaching session, in which we discussed various aspects of plagiarism. We subjected the data obtained from the quiz and questionnaire to bivariate and multivariate analysis. A total of 423 medical students participated in the study. Their average score for the quiz was 4.96±1.67 (out of 10). Age, gender and years in medical school were not significantly associated with knowledge regarding*

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