THE CURRENT STATUS OF PALLIATIVE CARE IN INDIA



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Less than 1% of India's 1.2 billion population has access to palliative care. The efforts by pioneers over the last quarter of a century have resulted in progress, some of which may hold lessons for the rest of the developing world. In recent years, a few of the major barriers have begun to be overcome. The South Indian state of Kerala, which has 3% of India's population, stands out in terms of achieving coverage of palliative care. This has been achieved initially by non-government charitable activity, which catalysed the creation of a government palliative care policy. The non-government action, by involving the community, serves to strive for quality of care as the government system improves coverage. On the national level, recent years saw several improvements, including the creation of a National Program for Palliative Care (NPPC) by the government of India in 2012. The year 2014 saw the landmark action by the Indian Parliament, which amended India's infamous Narcotic Drugs and Psychotropic Substances Act, thus overcoming many of the legal barriers to opioid access. Education of professionals and public awareness are now seen to be the greatest needs for improving access to palliative care in India.

ome to one-sixth of the World's population, India has a huge burden of suffering from life-limiting diseases. Less than 1% of its population has access to pain relief and palliative care (1). It has a federal system of Government, health and drug control being responsibilities of its 29 states and six Union Territories. Provision for health care and for opioid access varies from state to state, and as can be expected, this created difficulties especially when one state had to depend on a manufacturer of opioids in another state or when palliative care provisions had to be made a part of Government's health system.

Palliative care was born in India as the Shanti Avedna Sadan in Mumbai, a hospice, in 1986 (2). Over the next five years, it established two more branches, one in Delhi and one in Goa; but patients outside these institutions had no access to palliative care. Two major developments occurred in the 1990s. One was the formation of the Pain and Palliative Care Society (PPCS) in Calicut in the South Indian state of Kerala in 1993. The other was the formation of the Indian Association of Palliative Care in 1994.

PPCS was formed as a registered charitable trust. It followed the work of the author over the previous six years to provide a pain management service in the Government Medical College Hospital. It was obvious that for any person with pain, the suffering goes way beyond pain as a symptom.

They often have other symptoms along with psychological, social and spiritual issues often complicated by impoverishment. Typically, all treatment costs were out of pocket for the patient. It was not easy to watch families getting destroyed, including the generation that follows the patient. This experience and teachings of visiting pioneers, particularly Ms Gilly Burn, a British nurse, brought to light the need for total care of the patient. Two doctors and one layman got together to form PPCS (3). From the point of involvement of this lay person, Mr Asok Kumar, the community was seen as an integral part of palliative care in Kerala.

The organization was started with practically no resources and was done purely based on volunteerism. As more volunteers got involved, PPCS grew as an out-patient service later adding on a home visit programme as the need became apparent. Dr Jan Stjernsward, then Chief of Cancer and Palliative Care at the World Health Organization (WHO), and Dr Robert Twycross, the director of the WHO Collaborating Center, Oxford, were major catalysts in this process.

This duo also catalyzed the formation of the Indian Association of Palliative Care (IAPC). Doctors from various parts of India, with a predominance of anaesthetists involved in pain management, formed the majority of founding members. From the beginning, the association envisaged a

multidisciplinary approach and welcomed volunteers as members.

Over the next few years, in the latter part of 1990s, several new palliative care initiatives were started, such as the Guwahati Pain and Palliative Care Society in Assam, the Jivodaya Hospice in Chennai, Cansupport in Delhi, the Lakshmi Palliative Care Trust in Chennai and the Karunasraya Hospice in Bangalore. Some regional cancer centres like Trivandrum, Bangalore and Delhi which already had pain management programmes, also included palliative care in their service. Though every year a few centres were added, the growth was limited considering the enormity of Indian population.

At this time, access to opioids was not easy. Possibly as a response to the global war on drugs, India had formed, in 1985, the Narcotic Drugs and Psychotropic Substances (NDPS) Act (4). This draconian legislation brought in stiff penalties which could even be applicable for minor clerical errors and gradually pharmacies stopped stocking morphine. This Act also mandated several different licenses, typically four to five, all of which needed to be valid at the same time. Typically again, these licenses had to be issued with the concurrence of several Government departments making the system next to non-functional. In the 13 years which followed the enactment of the NDPS Act, morphine consumption in the country fell by an alarming 92% - from around 600kg to a mere 48kg. In 1997, India's per capita consumption of morphine ranked among the lowest in the world (113th of 131 countries). During the same period, global consumption of morphine had increased by 437% (5).

In 1995, Mr David Joranson, the Founder Director of Pain and Policy Studies Group in Madison Wisconsin, another WHO Collaborating Centre, entered into a partnership with palliative care pioneers in India. They analyzed the NDPS Act, identified barriers and submitted a proposal to the Government of India for simplification. Health as well as control of opioid medicines are both "state subjects" in India's federal system of governance; it was necessary for each state to act independently (6).

In 1998, the pharmacologist Ravindra Ghooi approached the Delhi High Court seeking access to morphine for his mother in pain from cancer. The High Court passed an order expressing sympathy for the cause and asking Delhi Government to take prompt action. Following this and representations from the Pain and Policy Study Group, the Government of India prepared a model rule for the modification of existing state regulations and asked all states to change their regulations accordingly. By India's constitution, the state government is not obliged to follow

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the central government in this matter. Most states did nothing. The collaborators, namely the Pain and Policy Studies Group and Indian palliative care activists worked together through state governments. Eighteen workshops were organized in various states resulting in many of them changing the state regulations following the central government instruction.

Of these, Kerala showed a remarkable improvement in access to opioids during the subsequent years. Some states like Tamil Nadu, Karnataka and Delhi showed a modest improvement while in most other states the change was minimal. It appears that wherever there was existing palliative care activity resulting in a demand for pain relief and for morphine, the amendment of the state rules did improve the situation. It also became very clear that without such activity, the regulatory reforms make no impact.

Since the beginning of the Pain and Palliative Care Society in 1993, the community's involvement in palliative care was steadily growing in Kerala. By the turn of the century, this was given structure and growth with the name "Neighborhood Networks in Palliative Care" (NNPC) (7). An international conference on community participation in palliative care gave great visibility to NNPC, the media were supportive, public interest grew and truly the people of Kerala embraced palliative care. Trained volunteers are involved in palliative care, organizing palliative care services, doing nursing chores, educating families in care and in spreading awareness. Questions have been raised about the quality of services that such community-based services can give (8), but the system has indeed succeeded in providing a link between the patient and medical institutions (9), adding the "meso" element of the social capital that is being eroded in much of the world (10).

In 2003, the charitable organization called Pallium India was created to improve access to palliative care outside Kerala. Since then, palliative care centres have been established in 11 states where until then practically no such

service existed. Whether they followed the complicated old "narcotic" rules or the simpler new ones in some states, access to morphine became a reality in all these centres soon after the initiative.

In 2005, Pallium India submitted a representation to the Government of Kerala and to the Government of India for the creation of palliative care policy. The Kerala state government acted on it and created a task force to formulate a draft policy. Many meetings and discussions later, in 2008, the Government of Kerala declared a palliative care policy integrating it into health care (11). This has since then been a huge success so that today each of about 900 local selfgovernment institutions called *panchayats* employ one nurse trained in palliative care. The funds for this came through the National Rural Health Mission which, by the very function of its being, had to serve rural areas and therefore had to restrict their activities to community health centres and primary health centres. No budget allocation, unfortunately, was made for much of the activities envisaged in the palliative care policy, namely, the creation of palliative care centres in district hospitals and in tertiary referral centres. This has resulted in the anomalous situation in which the patient has to go through intolerable pain and other distress for weeks, months or years of treatment in major hospitals, to get palliative care only in the last few weeks at home through the primary health centre. The monitoring committees planned in the state policy were also not established and hence there was no forum for review and modification of strategy.

The Government of India formed a committee in 2006 involving experts from various parts of the country to create a national policy for palliative care. The committee worked together to create a draft policy document. However, following a change in one official, this did not see the light of the day. Representations to the Medical Council of India and Indian Nursing Council for the incorporation of palliative care into the undergraduate curriculum also were unsuccessful during that decade.

Following the initial growth in the 1990s, there appeared to be a plateauing of improvements in palliative care access at the national level in India. In 2007, palliative care activists took the matter to the Supreme Court of India. The petitioners were the Indian Association of Palliative Care (represented by the Chairman of its Opioid Availability Committee), Dr Ravindra Ghooi who had earlier taken the matter to Delhi High Court and Ms Poonam Bagai, a cancer survivor and founder of Cankids, a child cancer organization and Vice Chair of Pallium India. Two Supreme Court lawyers, Mr Ashok Chitale (one of the trustees of Pallium India) and

Niraj Sharma, gave their services gratis for this purpose. The Supreme Court accepted the case in file which in itself was a success because only about 7% of all submitted petitions are usually accepted by the Supreme Court. The petitioners argued that lack of access to palliative care violated an individual's fundamental right to life with dignity that was guaranteed by the constitution of India and asked essentially for three things:

- ➤ the central and state governments should develop palliative care policies;
- ➤ the NDPS Act of India must be simplified ensuring access to opioids for those who need them; and
- palliative care must be made a part of undergraduate medical and nursing curricula. During periodic hearings of the case which is yet to be settled, the court's questions to the central and state governments have been a significant factor in catalyzing action.

A further development occurred in Kerala between 2005 and 2008. Acting on a request from Pallium India, the Government of Kerala appointed a committee to draft the Palliative Care Policy for the state. The policy came into being in April 2008. It accepted palliative care as an essential part of health care in the state. However, the Government made no budget allocation for palliative care and the implementation of palliative care was left to the National Rural Health Mission (NRHM). This has been largely successful.

Kerala, though it covers only 1% of India's land mass and cotains 3% of India's population, has now more palliative care services than the rest of the country put together. In a study published in 2008 (12), McDermott E et al found Kerala to have 83 palliative care services as against 139 in the whole of the country. As of 2014 in Kerala, more than 170 institutions stock and dispense oral morphine.

International advocacy has always had a major role in supporting palliative care efforts in India. In 2009, the Human Rights Watch published the results of their research, namely "Unbearable pain: India's obligation to ensure palliative care" (13). One of its recommendations was to International Narcotics Control Board (INCB) to plan a fact-finding mission to India, with the availability of controlled substances for medical and scientific purposes as one area of focus. INCB did take up the suggestion and a delegation came to India and interacted with Government officials and representatives of palliative care associations. Its recommendations had a major role in persuading further government action. India, till around this time, did not have a proper system in place for assessing opioid consumption and

reporting it to INCB and for many years, it either failed to send reports or sent clearly inaccurate reports. Following the INCB visit, the Government put into place a new functional system and from that year, we have had reasonably reliable statistics on consumption of opioids.

Recognizing that education of professionals was the key to improvement of palliative care in the country, palliative care activists had, from the beginning, conducted educational programmes. After several trials with courses of two, four and six weeks, the six week courses in Palliative Medicine and Nursing started by PPCS became widely popular and has been replicated in several institutions in the country. A one-year fellowship programme was also started by several institutions, though none had the approval of the Medical and Nursing Councils of India.

Continued advocacy by the palliative care community bore fruit in 2010, when the Medical Council of India accepted palliative medicine as a medical specialty and announced a postgraduate course in the subject. Subsequently, in 2012, the first Doctor of Medicine (MD) course was started at the Tata Memorial Hospital in Mumbai with two places per year. Unfortunately, most of the palliative care service available at this time was in the charitable sector, and there are not many academic institutions with the capacity to start palliative care courses.

Designation of the Institute of Palliative Medicine at Calicut, Kerala, as a WHO Collaborating Centre for Community Participation in Palliative Care and Long Term Care in 2010 and of Pallium India's Trivandrum Institute of Palliative Sciences (TIPS) as a WHO Collaborating Centre for Training and Policy on Access to Pain Relief in 2012 were two significant events contributing to further progress.

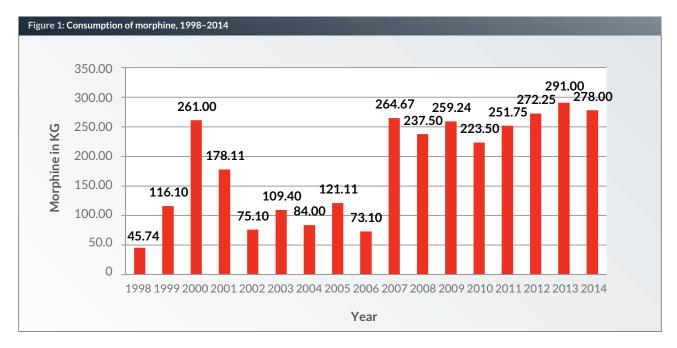
In 2013, following his attendance of a side-event held at the World Health Assembly in Geneva organized by Human Rights Watch and others, the Principal Secretary of Health of Government of India, Mr Keshav Desiraju, called a meeting to create a palliative care strategy for the country's five-year plan. Health ministry officials and palliative care activists worked together to create this strategy, the National Program in Palliative Care (NPPC), which was declared in 2012. Unfortunately, the proposed budget allocation did not materialize and hence, the implemented part of NPPC turned out to be a skeleton of the envisaged programme, with about 2% of the originally proposed budget, some money being allocated to a minority of states by the Government of India for implementing some of the parts of the NPPC.

Pallium India found the resources and organized a working group to create an implementation framework for NPPC,

spelling out strategies, action items, and timelines. This was submitted both to the WHO India Office with a request for undertaking operational analysis and to the Ministry of Health. Though the operational analysis did not materialize, the document continues to be available for guidance in implementation of NPPC (14).

In addition to implementing the establishment of palliative care services, the NPPC had recommended undergraduate medical and nursing education as one of its targets. Pallium India subsequently organized a working group involving experts from various parts of the country, Ministry of Health officials and representatives of the Medical Council. The committee, over a six-month period of time, developed curricula for undergraduate medical and nursing education, and prepared a scheme for its inclusion in the existing medical and nursing curricula. Action on this by the respective councils is yet to happen.

The Pain and Policy Studies Group at Madison, Wisconsin, in 2012, included three fellows from India in its fellowship programme and also invited two officials from the Government of India, Mr Rajesh Nandan Srivastava, Director of Narcotics in the Department of Revenue, and Dr Sudhir Gupta, Deputy Director General of Health Services. Their interactions had a positive impact, and in the subsequent year, the department of revenue, working with palliative care activists, developed a draft document for amendment and simplification of the existing NDPS Act. The voluntary services of a lawyer, Ms Tripti Tandon of the nongovernmental organization "The Lawyers' Collective" had given precious input to the drafting of this document. The Amendment would have the effect of uniform NDPS rules for the whole country, as it would shift the powers of legislation from the state government to the central government. The resultant document was placed before the Parliament of India in 2013. It was on the agenda for all three sessions of the Indian Parliament during 2013, but never got the required priority to be dealt with, despite advocacy campaigns by the palliative care community. Finally, during an extended winter session of the Parliament in February 2014, the Parliament passed the NDPS Amendment Act. The new Act transferred the powers for legislation on "essential narcotic drugs" (ENDs) from the state governments to the central Government. It is necessary now for the Government of India to announce the uniform simplified state rules. These rules and the standard operating procedures were already prepared by the government, in consultation with the department officials with the support of Ms Tripti Tandon of Lawyers' Collective and palliative care activists. In May 2015, the Government of India concluded the process



with notifications regarding the rules to be followed by the state governments. It is up to palliative care activists and state governments to ensure that the amended rules are implemented.

If we take morphine consumption in the country as the index of access to palliative care, there has been little progress in last few years as can be seen in Figure 1 (15).

Considering that the official reporting of data to INCB has been erratic until recently, this graph has used the officially communicated record of the quantity of morphine sold by the Government opium and alkaloid factory to manufacturers of formulations of morphine. Considering that morphine is the only oral opioid belonging to step III of the WHO analgesic ladder, these figures are likely to be representative, with some exceptions. In 2000, the peak was caused by a large scale purchase of morphine by the Government of India using funds from World Health Organization for free distribution to Regional Cancer Centres. We know for a fact that the bulk of it was never used and was eventually destroyed after expiry date. The drop in consumption from 2002 to 2006 was caused by a breakdown in the Government Opium and Alkaloid Factory, following which production of morphine was reduced.

Summary

There has been a lot of progress in palliative care in India, but the fact remains that despite the passing of almost a quarter of a century of palliative care activity in the country, even today palliative care reaches only about 1% of the people in India. If we take per capita consumption of opioids belonging to the step III of the WHO ladder as a criterion,

this has been on a plateau for many years now.

India is still at that phase when it seems poised to leap forward, though the dynamism is yet to be manifest, in the following three areas:

- ➤ The NDPS Amendment Act is simplified now, but needs to be implemented by state governments. Nongovernment palliative care organizations, who already are struggling with paucity of resources, will have to take on the onerous task of finding funds and personnel for catalyzing government action, state by state, through 29 states and six union territories.
- ➤ Despite a submission before the Supreme Court of India expressing willingness to incorporate palliative care in undergraduate curricula, and despite the palliative care community preparing the curricula and giving a framework for implementation, the Medical Council of India and the Indian Nursing Council are yet to act on the matter.
- ➤ Though the National Program in Palliative Care was created in 2012, due to lack of budget allocation, only a tiny part of the programme has been implemented. Even for the part that is funded, considerable catalytic work is needed with the state governments to ensure that proper plans are made and implemented.

In short, some major barriers to access to palliative care in India have been overcome, but implementation of created policies and laws still requires massive efforts by both the government system and non-government organizations. The non-government organizations do have the commitment but would need international support to effectively facilitate

government activity.

The recent declaration by the World Health Assembly (16) asking all member states to integrate palliative care with routine health care comes as a major tool in advocacy and hopefully will boost the current efforts. •

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He has contributed significantly to the Amendment of India's NDPS Act in 2014, the development of the Kerala Government's policy on Palliative Care and Government of India's National Palliative Care Strategy in 2012.

In 2014, Human Rights Watch honoured Dr Rajagopal with the Alison Des Forges Award for Extraordinary Activism.

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ISOPP: PROMOTING ONCOLOGY PHARMACY PRACTICE WORLDWIDE TO IMPROVE PATIENT CARE

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he value of the oncology pharmacist as a collaborative member of an interdisciplinary cancer care team to best support the complex drug therapy needs of the individual with cancer has been recognized and described in the literature (1). Oncology pharmacists are viewed as the cancer drug therapy experts in many countries, based on their training, expertise and function. The role of the oncology pharmacist has evolved to address many aspects of direct patient care and to support overall cancer care. The role continues to evolve worldwide through the dedication and efforts of oncology pharmacists, local, national and regional oncology pharmacy organizations and ISOPP. The advancement of the role of the oncology pharmacist is key in emerging health systems.

ISOPP, the International Society of Oncology Pharmacy Practitioners, is a nonprofit organization that celebrates 20 years this year. ISOPP's mission is to promote and enhance oncology pharmacy practice worldwide to improve cancer patient care. This mission is accomplished through development and dissemination of practice standards related to oncology pharmacy practice, as well as the development and provision of oncology pharmacy education. The organization supports educational initiatives, promotes and sponsors oncology pharmacy research and provides a forum to optimize both formal and informal networking for oncology pharmacists.

As cancer care continues to progress, it is essential to evaluate changes in cancer drug therapy as well as oncology pharmaceutical care to successfully integrate advances in care into practice as appropriate. A global approach to the evolution is not always appropriate. There is a need to ensure that resources are available to integrate and support integration as countries and regions around the world incorporate changes. ISOPP provides a platform for oncology pharmacists to share ideas and strategies that can be adapted across the world, as well as identify resources a individuals) that have been part of successful changes are their environment. The Journal of Oncology Pharmacy (January 1999), the official publication of ISOPP, provides

the opportunity for members to learn of practices, practice innovations and the individuals who have innovated from across the globe. This forum provides information and shares ideas. JOPP publishes original articles relevant to oncology pharmacy practioners across the oncology pharmacy specialty. Meeting abstracts for the ISOPP symposiums are published in JOPP ensuring that highlights from the emerging work of pharmacists to optimize oncology care are widely available. This also provides information about potential resources for members as they look to implement ideas within their region. JOPP is available in both online and hard-copy formats and is indexed in the PubMed database, International Pharmaceutical Abstracts as well as other medical literature databases. This ensure that information is available to pharmacists and health-care professionals across the globe and helps provide access to information for those unable to participate in ISOPP symposia.

ISOPP has developed and published Standards of Oncology Pharmacy Practice that provide guidelines for many aspects of oncology pharmacy practice, and take into account the realities of oncology pharmacy practice from both resource-rich and resource-poor settings. These standards address key issues for pharmacists and the healthcare team regarding topics important to managing drugs and drug therapy, preparing cancer treatment, and administering chemotherapy/cancer therapies. The ISOPP standards focus on aspects of sterile and safe handling of cancer medications, strategies to optimize safety, such as the appropriate use of personal protective equipment, prevention and management of chemotherapy spills, and optimization of the drug therapy process to minimize and manage medication errors. These standards continue to evolve as the practice of oncology pharmacy and cancer care evolves and are currently being updated. Additionally, many national pharmacy and/or health-care organizations have developed standards that provide additional and complementary guidance on oncology pharmacy practice. ISOPP partners with these groups to help disseminate information to members throughout the world that may benefit from this work.

The availability of new drugs and drug combinations for the management of cancer, cancer-related complications and treatment-related complications introduces a new challenge of ensuring all members of the cancer care team keep apprised of developments. Educational offerings that focus on the changes in care are provided through live programming, enduring materials on the ISOPP websites, and through editions of the Journal of Oncology Pharmacy Practice. ISOPP is committed to providing members with regional and international education opportunities to support both formal and informal networking, ultimately advancing oncology pharmacy practice.

There are emerging issues, advances and challenges in oncology pharmacy and ISOPP provides the opportunity for pharmacists around the world to jointly discuss concerns and consider solutions using ISOPP forums. Many of these challenges involve the clinical application of new treatments and considerations required to prevent, minimize, manage and identify the long- and short-term treatment-related complications.

Examples of topics addressed in ISOPP educational forums include:

- Cost of cancer care. The cost of drugs used in treatment of cancer account for a high percentage of medical cost (2). The cost of medications impacts accessibility of treatments for many individuals worldwide. Rising costs have led to theft and diversion of drugs in some areas, resale of drugs on "black markets", and/or the use of substandard or counterfeit drugs.
- Oral anticancer drugs. The evolution of oral anticancer agents in cancer therapy, and the challenges and opportunities associated with the use of these agents, has become an important discussion for the cancer care team. Strategies to optimize care for individuals with cancer on oral or oral/parenteral drug therapy are frequently published in Journal of Oncology Pharmacy Practice and/or presented at ISOPP symposia including tools to improve medication adherence, optimization of access to drug therapy, management of drug-drug interactions and cost of care.
- > Oncology drug shortages. The enduring challenge of

- oncology drugs shortages across the world (3) has been addressed by ISOPP and through other oncology pharmacy organizations.
- ➤ Biosimilars and cancer care. The availability of biosimilar anticancer therapy varies between regions and countries, and sharing ideas and experiences has helped ISOPP members address questions in their local areas.
- Expanding role of oncology pharmacy and the professional development of pharmacists throughout the world is a current focus for the organization.
 Planning is ongoing to determine strategies for ISOPP and/or collaborations with ISOPP to support the development of oncology pharmacy globally.
- Development of clinical guidelines for optimization of care of the individual affected by cancer, including both treatment and survivorship issues.
- Optimization of drug therapy in select patient populations (e.g. elderly, individuals with organ dysfunction).
- > Patient and caregiver-directed education.

Since the ability to discuss issues and learn from colleagues from across the world is invaluable, ISOPP encourages the development of evidence-based recommendations through the support of oncology pharmacy research and interdisciplinary research. ISOPP is committed to supporting the efforts of oncology pharmacists in research efforts to help answer the questions in optimizing drug therapy as well as optimizing oncology pharmacy systems. The support of research ultimately leads to a better understanding of practice, and contributes to improvement in patient care.

ISOPP continually seeks opportunities to promote and enhance oncology pharmacy practice worldwide to improve cancer patient care. There are many barriers to providing optimal cancer care to individuals throughout the world. The issues listed above are complex, and the likelihood of success is greater through collaboration. •

For more information

http://www.isopp.org

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