

Basic Certificate in Palliative Care
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Indian Institute of Technology, Kanpur

Week-12

Lecture 03: Availability of ENDS and Advocacy

Hi, greetings from International Institute of Distance Learning, the academic division of National Association of Palliative Care for Ayush and Integrative Medicine. I am Doctor Piyush Gupta, secretary of National Association of Palliative Care for Ayush and Integrative Medicine and secretary and principal executive officer of Cancer Aid Society.

So, in this presentation we will be talking about essential narcotic drugs and advocacy. So, first of all let us understand what is the meaning of essential narcotic drugs. So, before 2015 according to Narcotic Drugs and Psychotropic Substances Act. So, all those drugs were part of NDPS Act and including which includes morphine also, opium, morphine and other narcotic drugs and possession of these drugs needed a license and it was very difficult to get the license even for oral morphine which is the World Health Organization's gold standard for treatment of pain of the cancer patients.

After 2015 some of the medicines which we will be explaining later which are used for treatment of cancer pain were brought out from that act and we already know that license of narcotic drugs is given by excise officials whereas, these medicines for treating the pain of the patient they were brought out from the purview of narcotic drugs and psychotropic substances act from exercise department its license was now to be issued by drug controller of the state and we all know that drug controller gives license for medicines etcetera. So, it is easier for people to get license from drug controller and it was very difficult in getting licenses from the excise department which normally gives licenses for things like alcohol. So, in 2015 these drugs which were used for treatment of cancer pain they were called as essential narcotic drugs and we will be talking about these as well as how we can get its availability about the license procedure and after

availability how we have to maintain the records. So, that all we will be understanding in this presentation.

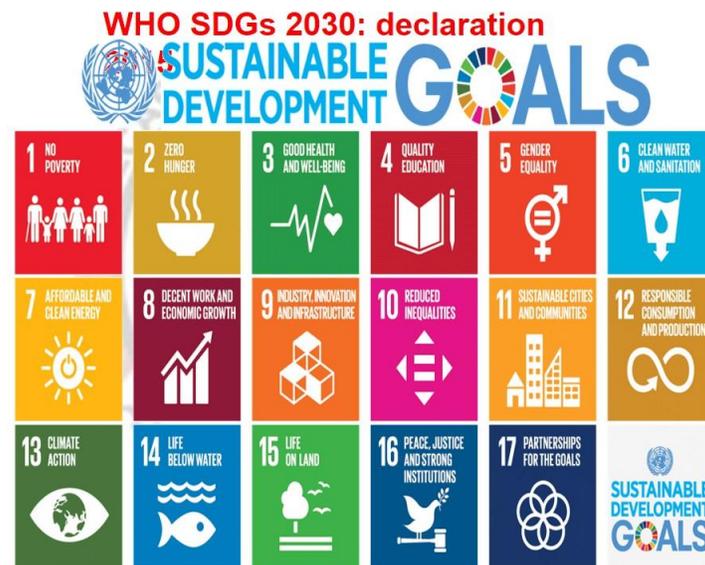
Now, next word is advocacy. So, what do you understand by the term advocacy? So, normally we know what advocates do. They fight for your cause with the judge they put your cause before the judge. So, similarly the issues which are for others which are social concerns. So, you have to get up, you have to rise to the occasion and sensitize others about those issues and one very important issue is treating the pain of the patients because most patients they suffer from tremendous pain and they curse themselves for none of their sins they ask the god to take their lives early, but they have not done any crime they are suffering from a disease and their pain is very much treatable, but since the medication which can treat their pain it is covered under NDPS act hence their pain is distant from being treated. So, you have to understand that after attending this presentation it is not only for reading, but you have to become an advocate you have to sensitize the government and other officials and even the doctors that they should not ignore the pain of the patients they should learn to address the pain of the patients and let us say oral morphine is very important for treating their pain and if it is not available in the market, neither it is available in their hospitals then what happens even if you want to use it you cannot use it.

So, availability of oral morphine you have to advocate in the government hospitals, you have to advocate in the private hospitals that they should bring this tablet which hardly cost 2 rupees and rather than getting a tablet of 2 rupees people shell thousands and thousands of rupees just for treating their pain and which again is not treated properly. So, remember we have to ensure that oral morphine becomes available across the country at least in government hospitals and some private hospitals who have palliative care professionals working with them.

So, you will have to sensitize those government hospitals train them on to the issues of availability of oral morphine sometimes the even the licensing authorities may not be aware about the new rules. So, you will purchase the NDPS amended act of 2015 and you will show them the chapter 5b which covers about the essential narcotic drugs and you

can refer we have all we will be covering in this presentation about the various sections various forms and you can use it as a guidance and you can show it to the competent authorities and that is how once you make the oral morphine available across the country really you will be treating the pain of the people who are in deep anguish and who curse themselves for none of their sins.

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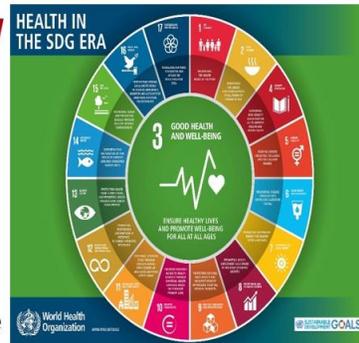
So, let us carry on with this we have to again understand that by 2030 we have to achieve these 17 goals which were drafted by United Nations sustainable development goals and all the UN members were signatories to this.

Here we can see that goal number 3 is good health and well being.

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Keeping up with the Sustainable Development Goals 2030, Goal 3 is “Good Health and Well Being”

- **“Good Health” aims to keep the global citizens healthy & disease free whereas “Well Being” points towards Palliative Care i.e. taking care of the sufferings due to illnesses.**



So, when we are talking about sustainable development goals goal number 3 good health and well being. Now, good health aims to keep the global citizens healthy as well as disease free, but what do we understand by the term well being. Now, this points towards palliative care and what is palliative care you must be knowing by now, taking care about the sufferings of the people due to various illnesses and improving their quality of life and one very important symptom which is often ignored by the doctors by the family and friends is pain. Remember this pain is treatable, but most of the time we learn to stay with the pain rather than getting it treatable.

So, you have to tell all those people who are suffering in pain that the pain can be treated and they should go to a palliative care doctor who will treat their pain because normal doctors who are treating the cancer they do not have time to address to the other symptoms of the patients and many times they these patients are into deep anguish due to severe pain which could be physical pain or it could be mental pain too along with social psychological and spiritual issues and this is possible only by a palliative care professional to address the various pain of the patient.

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At United Nations High Level Meeting on Prevention and Control of NCDs in 2011 & Review Meeting 2014



So, here you can see me participating in the high level meetings on NCDs at United Nations in 2011 and subsequent review meeting in 2014 and that was the starting of the fight against non communicable diseases globally.

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Organising Secretary of 18th International Conference of IAPC at SGPGIMS Lucknow



GCM/NCD Meeting April 2015 at WHO Head Quarters Geneva



So, well I was organizing secretary of 18th international conference of Indian association of palliative care at Sanjay Gandhi post graduate institute of medical sciences Lucknow and after that in 2015 April I had participated at world health organization headquarters Geneva on the meeting of global coordination mechanism on non communicable diseases.

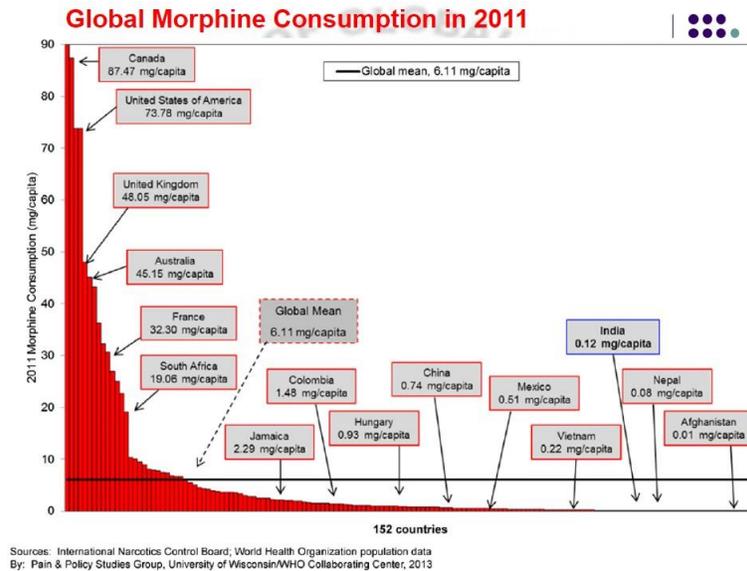
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GCM/NCD Meeting November 2015 at WHO Head Quarters



This was the second meeting at WHO Geneva headquarters in November 2015 and you can see me attending the meeting and getting engaged in the dialogue over here and this is the representation of cancer aid society within UN WHO office at Geneva.

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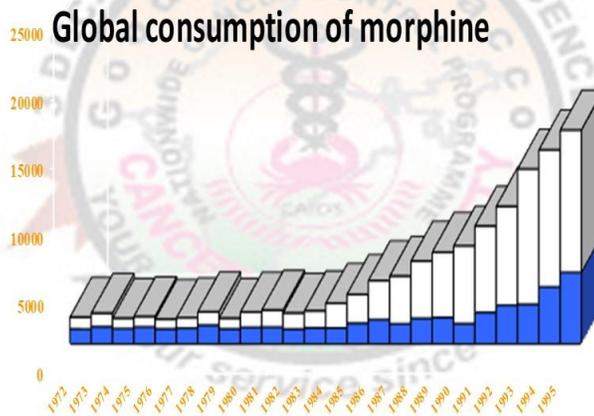


So, when we are talking about global morphine consumption you can see the graph and here we can see that there are countries who are on top using the maximum morphine and you can find India which is having the largest population of the country hardly using any morphine.

This shows that our patients are in tremendous pain.

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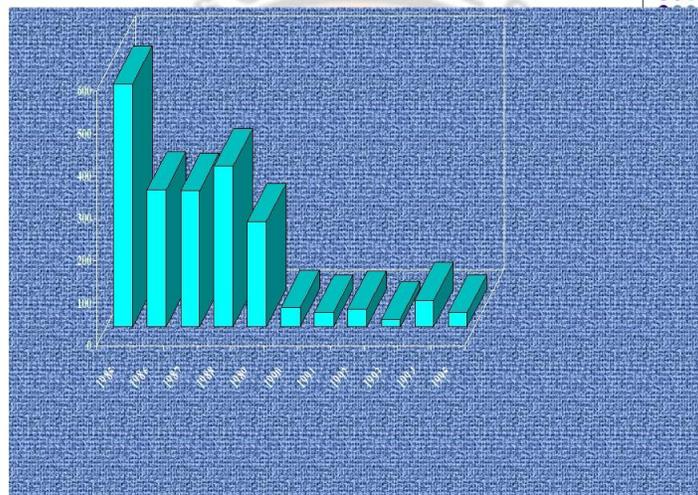
Global Morphine consumption 1972-95



Now, this is the slide where we are seeing that down the line morphine consumption is using across the world, but nothing has improved in India.

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Morphine consumption in India 1985-95



So, let us see the morphine consumption in India from 1985 to 1995 and we see all of a sudden this graph is going down. So, we were using morphine effectively, but down the line it is going to the bare minimal position.

What are the reasons for this decline in morphine usage?

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- **The Complexity of Narcotic Drugs and Psychotropic Substances Act, 1985 in line with International Conventions made availability of Oral Morphine complicated.**

Different States framed different rules and multiple licensing system for Possession/ Export/ Import/ involving Excise / Drug Controller

So, the complexity of narcotic drugs and psychotropic substances act 1985 along with the international conventions it made availability of oral morphine very complicated.

Different states framed different rules and there were multiple licensing system for possession, export, import involving exercise along with drug controller.

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To address the above problem at National Level through effective Advocacy

Cancer Aid Society Organized 33 workshops on Palliative Care & Oral Morphine since 2007-2019 in Govt. Medical Colleges, RCCs in the States of U.P., M.P., Bihar, Jharkhand, Chhattisgarh, Assam, Punjab and Tamil Nadu.

Created environment for starting of Pain Clinics and availability of Oral Morphine.

Organized CME in Pain Management for Final Year MBBS Students of various Medical Colleges in Collaboration with SGPGIMS Anesthesia Department.

Advocacy for implementing directives of Honorable Supreme Court dated 24/08/2012, to State Governments for making Oral Morphine available for treating the pain of terminally ill Cancer Patients.

Now, to address the above problem at national level cancer aid society got involved in effective advocacy and this was under the grant of American cancer society. So, we organized 33 workshops on palliative care and oral morphine since 2007 to 2019 in various government medical colleges, regional cancer centers in the states of UP, MP, Bihar, Jharkhand, Chattisgarh, Assam, Punjab and Tamil Nadu. We created an environment for a starting of pain clinics and availability of oral morphine and the effort continues even till date. We organized CME in pain management for final year MBBS students of various medical colleges in collaboration with SGPGIMS Anesthesia Department.

We got involved in advocacy for implementing directives of honorable supreme court dated 24-8-2012 to the state governments for making oral morphine available for treating the pain of terminally ill cancer patients.

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**Effective Advocacy by Cancer Aid Society for Palliative Care
And Morphine Availability**



Organized 18th International Conference of Indian Association of Palliative Care 2011 at Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow which changed the scenario in the Country. Instituted Award for Leadership in Palliative Care in SAARC Countries for Rs.1 Lac INR in 2011.

**Drafted Palliative Care Declaration 2011 -
the first ever at International Level for effective Advocacy.
Financial Assistance to over 2200+
Cancer Patients towards Palliative Care.
Contributed in Amendment of NDPS Act as
Member of the Committee for suggesting changes in the Act.**

As I told you we organized the 18th international conference of IAPC and here we announced rupees 1 lakh annual award for leadership in palliative care amongst our countries. So, that was the first ever international award announced by cancer aid society. We drafted a palliative care declaration, the first declaration across the globe in 2011. We provided financial assistance towards palliative care to over 2200 more patients.

We have contributed in amendment of NDPS act and on behalf of cancer aid society I was member of the committee for suggesting the changes in NDPS act.

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Timeline

First Workshop in UP at SGPGIMS Lucknow on 17th March 2007.
At CSMMU Medical College Lucknow on 1st Dec-07..
At LLRM Medical College, Meerut on 26th April-08.
At RLB Medical College, Jhansi on 13th Dec-08.
At Dept. of Anaesthesiology, GSVM Medical College, Kanpur on 2nd August, 2008.
At Dept. of Anaesthesiology, SN Medical College, Agra on 18th September 2008.
At Dept. of Anaesthesiology & Critical Care , M.L.B. Medical College, Jhansi on 13th December 2008.
One Day Review Meeting on "Cancer Pain Management vis-à-vis Oral Morphine" on 10th February 2009 in Regional Cancer centre, SGPGIMS, Lucknow.
At Cancer Institute, Adyar Chennai on 18th July 2009.
At BRD Medical College, Gorakhpur on 16th December 2009.
Organised a series of Lectures for the Doctors of SGPGIMS, CSMMU and Social Workers of Cancer Aid Society at Lucknow February 2nd 2010.

Organised a five day Toolkit Training in Palliative Care from 21st to 25th June 2010 at SGPGIMS Lucknow.
At Patna Medical College on October 23rd, 2010.
At Raipur Medical College on October 30th, 2010.
Organised the 18th International Conference of Indian Association of Palliative Care from 11th to 13th of February 2011 at SGPGIMS Lucknow, and Preconference workshop at CSMMU which was attended by 400 Palliative Care Professionals coming from all over the World and India.
At Rajendra Institute of Medical Sciences, Ranchi on March 26th 2011.
At Gandhi Medical College, Bhopal on September 12th 2011.
At GSVM Medical College Kanpur on January 7th, 2012.
At Ram Manohar Lohia Hospital Lucknow on 8th September 2012.
At Rural Institute of Medical Sciences Safai on 13th September 2012.
CME on Pain Management at King Georges Medical University in May 2013.
CME on Pain Management at MLB Medical College Jhansi on 30th November 2013.
CME on Pain Management at BRD Medical College Gorakhpur on 29th March 2014.
At Guwahati Medical College Assam on 7th November 2014.

So, you can see we have organized workshops in the various institutions across the country and this even continues till date.

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At BSF Headquarter Jalandhar in April 2014.
Organized National Conference on "Role of Spirituality in Palliative Care" on 8th December 2016.
Organized National Conference on "AYUSH Intervention in Palliative Care" on 8th December 2017.
One Day Workshop conducted in Mirzapur District Hospital on 5th February 2018
One Day sensitization program was conducted in ERA's Medical College in April 2019.
One Day sensitization program was conducted in St. Mary's Nursing College in April 2019.
Sensitization program for different departments was conducted at ERA's Medical University ON 2nd, 3rd & 4th July 2019.

So, there is a huge list of our workshops.

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Workshops trained thousands of Doctors on Palliative Care and Oral Morphine thus benefitting Lacs of Patients and creating compatible atmosphere in North India.

On the eve of IAPCON 2011, MCI announced MD course in Palliative Medicine which was a long pending demand. Chairman MCI in his message suggested us "to come out with practicable strategies, which could be affected by the Council in coming times".

Debate in IAPCON 2011 was on "Euthanasia is humane care in face of suffering". In March Hon'ble Supreme Court Legalized Passive Euthanasia – Times of India 8/3/2011.

Honorable Supreme Court on 24/08/2012 directed the Chief Secretaries of State Governments to make Morphine preparations available for treating the pain of terminally ill Cancer Patients.

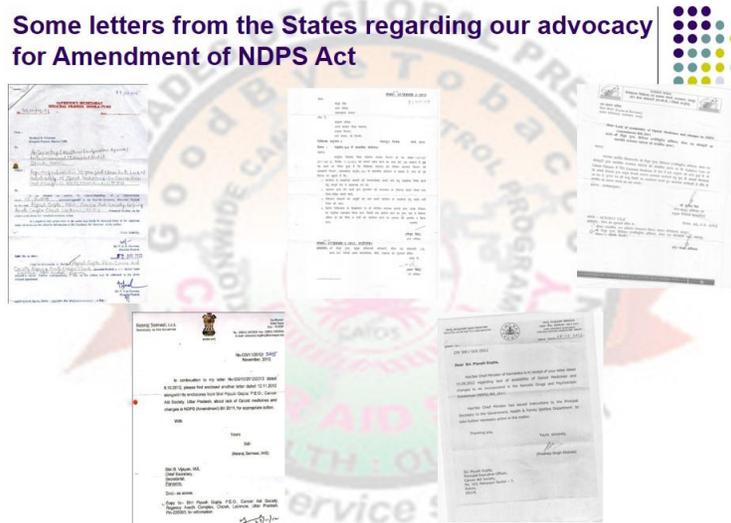
Future Plans: After achieving the above Goal, we stand committed for its implementation across the Country by taking it once again with the State Governments and improve the availability of Oral Morphine thereby taking away the pain of the Cancer Patients.

We have trained thousands of doctors in palliative care as well as oral morphine which has benefited lakhs of patients and created compatible atmosphere in North India because earlier this palliative care was confined only to the state of Kerala and cancer aid society with its initiative brought it across North India. So, on the eve of IAPCON 2011 MCI

announced MD course in palliative medicine which was the long standing demand of palliative care professionals.

The chairman MCI in his message to cancer aid society suggested us to come out with practical strategies which could be affected by the council in the coming times and his goodwill shows the improvements in palliative care. Debate in IPCON 2011 was on euthanasia is human care in face of suffering and in March Hon'ble Supreme Court legalized passive euthanasia which we all know was widely covered across the country in newspapers. Honorable Supreme Court on 24th of August 2012 directed the chief secretaries of state governments to make morphine preparations available for treating the pain of terminally ill patients. Now, after achieving the above goal we stand committed for its implementation across the country by taking it once again with the state governments and improve the availability of oral morphine thereby taking away the pain of the cancer patients. And for your information cancer aid society has got lead grant of international association of palliative care for the year 22, 23, 24 and 24, 25 for achieving this goal.

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Here you can see that our advocacy during NDPS amendment act with the various state governments because being a subject of state as well as center the state governments

recommendations were very important for amendment of NDPS act and this was delegated to us which he had we had effectively covered.

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Our letter to the Prime Minister was forwarded to the Finance Ministry and resulted in the amendment of the Narcotic Drugs and Psychotropic Substances Act where we were one of the Committee Members for finalising the changes, so as to improve the availability of Oral Morphine and other essential Drugs for improving the Palliative Care Services across the country.

So, our letter to the prime minister was forwarded to the finance ministry and resulted in the amendment of the NDPS act where we were one of the committee members for finalizing the changes. So, as to improve the availability of oral morphine and assert other essential drugs for improving the palliative care services across the country.

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Organised over 35 Workshops on Palliative Care & Policy
Circular of Excise Commissioner for licensing of Oral Morphine in U.P.

The collage consists of two main documents. On the left is a newspaper clipping from 'Times of India, Lucknow, March 18, 2007'. The main headline is 'PGI to use morphine against cancer'. A sub-headline reads 'Raising a question'. The article discusses the Sanjay Gandhi Post-graduate Institute of Medical Sciences (SGPGIMS) using morphine for cancer patients. It mentions a ban on morphine in India and the institute's efforts to procure it. On the right is an official letter from the Excise Commissioner, Lucknow, dated 10/10/2011. The letter is addressed to the Director, Narcotics Control, Lucknow. It discusses the issue of licensing oral morphine in UP and mentions a meeting held on 10/10/2011. The letter is signed by the Excise Commissioner, Lucknow.

So, here you can see what we had done in our advocacy across the country this is Times of India which has quoted it in a big way. And in UP, we have a UP model where the excise commissioner he simply sent a letter to all his subordinates for giving licenses to the government medical colleges and hospitals without fail and this had simplified the entire thing in UP in a big way.

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Advocacy with Government on availability of Essential Narcotic Drugs
 Letter to PMO / Health Ministry / Ministry of Finance

The document is an official office memorandum from the Ministry of Health & Family Welfare, Government of India. It is dated 23rd October, 2012. The subject is 'Two PMO references regarding lack of availability of Opioid medicines and changes in NDPS (Amendment) Bill, 2011'. The memorandum is addressed to the Director, Narcotics Control, Lucknow. It contains the following text: 'Please find enclosed herewith two letters received from Prime Minister's Office dated 27th September, 2012 and 28th October, 2012 on the subject mentioned above. You are, therefore, requested to reply directly to the applicant under intimation to this office for our records.' The memorandum is signed by the Under Secretary to the Govt. of India, Tel. No. 23012735. There are handwritten notes and dates in the left margin, including '4/23/12', '4/23/12', '4/23/12', and '4/23/12'. There is also a red box at the bottom containing the following text: '4/23/12, 6/6 Sh. Charu Vijay, Section Officer - w.r.t PMO ID No.9/3/2012-PMP4/435776 dated 27-09-2012. 4/23/12, 6/6 Sh. Pavan Malviya, Section Officer - w.r.t PMO ID No. 92/3/2012-PMP4/437676 dated 08-10-2012. 4/23/12, 6/6 Sevakendram, Pain & Palliative Care Unit, Komi P.O, Komi, Pathanamthitta. 4/23/12, 6/6 Sh. Piyush Gupta, Principal Executive Officer, Cancer Aid Society, 163, Nisbahpur, Sector-07, Rohini, Delhi'.

Ministry of Finance Constituted a Committee which drafted amendments and NDPS Act was finally amended in 2014 and notified in 2015 simplifying the licensing procedures

Ministry of Finance
(Department of Revenue)

North Block, New Delhi
October 05, 2012

Meeting Notice
Subject: NDPS (Amendment) Bill, 2011.

The undersigned is directed to refer to this Department's communication of even number dated 01.10.2012 on the above-mentioned subject and to say that the meeting convened by Revenue Secretary on Monday, the 8th October at 03.00 PM, to discuss the suggestions of industry associations like Organisation of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers Association (IDMA) and NGOs / associations associated with palliative care for amendment to the Narcotic Drugs and Psychotropic Substances Act, 1988, has been rescheduled to Wednesday, the 10th October 2012 at 11.00 A.M. The venue for the meeting will be "Kalpavriksha", Room No. 158A, North Block, New Delhi. It is requested to make it convenient to attend the meeting.

2. The inconvenience caused is deeply regretted.

(Signature)
S. N. Dasgupta
Under Secretary to the Govt. of India
Telephone: 91-11-231095419
E-mail: s.n.dasg@nic.in

To:

1. Chairman, Central Board of Excise and Customs, North Block, New Delhi.
2. Joint Secretary (IS-II), Ministry of Home Affairs, NDCC Building-II, New Delhi - 1.
3. Shri A. K. Panda, Joint Secretary (DDAP Division), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
4. Dr. Sudhir Gupta, Addl. DDG - Member Secretary, Expert Group on Palliative Care, Directorate General of Health Services, Nirman Bhawan, New Delhi - 110011.
5. Director General, Narcotics Control Bureau, West Block No.-1, Wing No.5, R.K. Puram, New Delhi-66.
6. Narcotics Commissioner, Central Bureau of Narcotics, 19, The Mall, Morar, Gwalior, Madhya Pradesh- 474006.
7. Drug Controller General (India), FDA Bhawan, Kotla Road, New Delhi-2.

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8. The Secretary-General, Indian drug Manufacturers Association, 102-B, Poonam Chambers, 'A' Wing, DR. A.B. Road, Worli, Mumbai - 400018.

9. The Director General, Organisation of Pharmaceutical Producers of India, Peninsula Corporate Park, Peninsula Chambers, Gr. Floor, Ganpatrao Kadam Marg, Lower Panel, Mumbai - 400013.

10. Dr. M. R. Rajagopal, Chairman, Pallium India Trust, PIRRA65, Pothujamam Road, Medical College P.O., Thiruvananthapuram - 695011.

11. Dr. S. N. Simha, President, Indian Association of Palliative Care, Institute of Palliative Medicine, Medical College, Kozhikode - 673008.

12. Dr. Anil Kumar Paleri, Hon. Secretary, Indian Association of Palliative Care, Institute of Palliative Medicine, Medical College, Kozhikode - 673008.

13. Ms. Harmaha Gupta, Founder - President, Cunn Support, Kanak Durga Basvi Vikas Kendra, Sector 12, R K Puram, Near New CGHS Dispensary, New Delhi 110022.

Shri Piyush Gupta, Principal Executive Officer, Cancer Aid Society, 163, Naharpur, Sector-07, Rohini, Delhi.

Copy to:

1. PS to RS / AS (R) / JS (R) / Director (NC)
2. GAR Section

So, this is we had sent a letter to prime minister office which was forwarded to the NDPS amendment act committee and you can see that after this we were invited to be a party for the amendment of NDPS act and here you can find me a part of the committee.

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Contributing in the amendment of NDPS Act in 2014



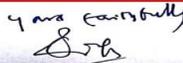
The Narcotic Drugs and Psychotropic Substances Act, 1985 has now been Amended and new Rules framed in 2015 where Cancer Aid Society was a Member of the Committee constituted by Govt. of India for suggesting Amendments however availability of Oral Morphine has yet not improved due lack of implementation.

We had deliberations and finally, the act was amended in 2015 it was notified and in spite of notification things have not improved because of lack of sensitization. Most of the government officials are not aware about the amended act and they are still following the old rules.

So, we have to sensitize others for the availability of oral morphine and this is known as advocacy.

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Licensing of chemists was not clear hence it was addressed by Drugs Controller General of India on our clarification.

7-5/2018/Misc/094 Directorate General of Health Services Government of India Central drugs Standard Control Organization (International Cell)	
To, Dr. Piyush Gupta, Secretary & Principal Executive Officer, Cancer Aid Society, 4 th Floor, Sunshine Court Phase II 66C Prag Narain Road, Hazratganj, Lucknow (U.P.) India-226001	05 SEP 2018
Subject: Defining Essential Narcotics Drugs under Schedule H of Drugs and Cosmetics Act-Reg	
Sir,	
This is with reference to your email dated 16/07/2018 wherein it is stated that the Essential Narcotics Drugs are defined in Chapter V-A Section 52-A(3) Table under the NDPS ACT however Essential Narcotics Drugs is not mentioned under the Drugs and Cosmetics Act Schedule H prescription drugs and it is requested to add the Essential Narcotics Drugs like Oral Morphine into the list of Schedule H drugs for licensing purpose.	
In this regards, it is to state that all the drugs coming under Narcotics Drugs & Psychotropic Substances are covered under Schedule H of Drugs & Cosmetics Rules 1945.	
 (Dr. S. Eswara Reddy) Drugs Controller General (India)	

In this amended act licensing for the chemist was not very clear.

So, we wrote a letter to the director general of health services and you can find that they had replied to our letter and they have clarified the issues related with licensing of chemist.

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Essential Narcotic Drugs



TABLE

Sl. No.	Name of the essential narcotic drug
(1)	(2)
1.	Morphine and its salts and all preparations containing more than 0.2 per cent of Morphine
2.	Methyl morphine (commonly known as 'Codeine') and Ethyl morphine and their salts (including Dionine), all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5% in undivided preparations and which have been established in therapeutic practice
3.	Dihydroxy Codeinone (commonly known as Oxy-codone and Dihydroxycodeinone), its salts (such as Eucodal Boncodal Dinarcon Hydrolaudin, Nucodan, Percodan, Scophedal, Tebodol and the like), its esters and the salts of its ester and preparation, admixture, extracts or other substances containing any of these drugs
4.	Dihydrocodeinone (commonly known as Hydrocodone), its salts (such as Dicodide, Codinovo, Diconone, Hycodan, Multacodin, Nyodide, Ydroced and the like) and its esters and salts of its ester, and preparation, admixture, extracts or other substances containing any of these drugs
5.	1-phenethyl-4-N-propionylanilino-piperidine (the international non-proprietary name of which is Fentanyl) and its salts and preparations, admixture, extracts or other substances containing any of these drugs

Scanned with CamScanner

Now, what are essential narcotic drugs according to the amended NDPS act the essential narcotic drugs the license has to be issued by drug controller and not excise department. So, oromorphine, codine, oxycodone, hydrocodone and fentanyl these are the essential narcotic drugs which are used for treating the pain of the patients.

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NDPS Chapter V-B: Recognised Medical Institutions

Sec 52-N: One registered medical practitioner with degree in medicine/ dentistry & training in Pain Relief & Palliative Care. Government Hospitals are deemed RMIs and exempted from application for RMI however all other provisions apply.

Sec 52-O: For Application of RMI/ Renewal in Form 3-F to the Drug Controller.

Certificate of Recognition in Form 3-G within 60 Days or reasons for delay by the Drug Controller.

FORM No. 3-F
[See Rule 52-O(1)]

Application for Issue/Renewal of Certificate of Recognition as Recognized Medical Institution

1.	Name and complete postal address of the institution with telephone number, telex/tele number and e-mail ID (relevant supporting documents to be submitted)	:	
2.	Name of the Head-in-charge of the Institution	:	
3.	Number of persons employed (i) Doctors (ii) Nursing staff (iii) Others	:	
4.	Number of patients treated during the previous calendar year (i) In patients (ii) Out patients (iii) Home care	:	
5.	Names of the qualified medical practitioners who would prescribe essential narcotic drugs (give details of their training in pain relief and addiction care or substance dependence treatment)	:	
6.	If there is more than one qualified medical practitioner who would prescribe essential narcotic drugs, indicate the name of the medical practitioner who shall be overall in charge	:	
7.	Number and date of the certificate of recognition issued earlier (attach copy)	:	
8.	Whether the recognition of the institution was withdrawn earlier (if the recognition was withdrawn earlier, the details are to be given)	:	

Date: _____ Signature: _____
Place: _____ Full name: _____
Seal: _____ Position: _____

FORM No. 3-G
[See Rule 52-O(2)]

Certificate of Recognition

No. _____ Date of issue: _____

This is to certify that _____ (Name of the institution) situated at _____ is a Recognized Medical Institution to possess, dispense and sell essential narcotic drugs.

2. The institution is a Recognized Medical Institution since _____ (mention date of the certificate issued for the first time) _____.

3. This certificate shall be in force from _____ to _____.

4. The certificate is subject to the conditions stated below and to such other conditions as may be specified under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules made thereunder.

Signature: _____
Designation: _____
Seal: _____

Conditions of recognition

1. This certificate is non-transferable.
2. This certificate and any certificate of renewal in force shall be kept on the approved premises and shall be produced in the request of an officer authorized for the purpose by the issuing authority.

Now, when we are talking about licensing of oral morphine some of the norms for its record keeping are very important and we will be covering those norms. So, kindly be very attentive and listen this.

So, first of all those institutions who get license they are known as recognized medical institutions and this you can cover in NDPS act chapter 5b if you want you can refer to that act. Now, section 52n says that one registered medical practitioner with degree in medicine dentistry and training in pain and relief and palliative care is important. Now, government hospitals are deemed RMIs and they are exempted from application for RMI. However, all other provisions are applied. Section 52o says for application of RMI renewal in form 3f has to be done to the drug controller.

So, earlier in some states it was excise controller in some states it was excise as well as drug controller. So, there was mixture of rules being followed in different states, but after the amendment all states have to follow the central rule. And certificate of recognition in form 3 g has to be issued within 60 days or they have to give the reasons for delay has to be given by the drug controller. So, here we can see the copy of form number 3f which is application for issue renewal of certificate of recognition as recognized medical institution. And we are here form number 3g is the certificate of recognition under NDPS act for license of essential narcotic drugs.

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Sec 52-R: Duties of registered medical practitioner
 Maintain following records for **2 years**
 Patients Record in **Form 3E**
 Receipt & Disbursement Record in **Form 3H**



FORM No. 3-E
 [See Rule 52-H(3)]
Details of the Patient
 To whom Essential Narcotic Drugs dispensed
 (To be maintained by Registered Medical Practitioner/
 Recognized Medical Institution)

Registration Number: Date:

1.	Name	:	
2.	Complete postal address (with contact number, if any)	:	
3.	Brief description of the illness	:	
4.	Whether registered with any other registered medical practitioner/recognized medical institution (If yes, details to be recorded)	:	
5.	Details of the essential narcotic drugs dispensed		
	Date	Name of the essential narcotic drugs	Quantity
		Signature/Thumb impression of the patient	Remarks, if any

Note:
 (1) This record shall be retained for two years from the date of last entry.
 (2) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.

FORM No. 3-H
 [See Rule 52-R(1)(c)]
**Daily Accounts of Essential Narcotic Drugs to be Maintained by
 Recognized Medical Institution**

Name of the Essential : Date :

Narcotic Drug		:	
1.	Opening stock	:	
2.	Quantity received	:	
2(a)	Received from (give details)	:	
2(b)	Consignment Note/Bill/Invoice/Cash Memo, Number etc.	:	
3.	Quantity dispensed	:	
4.	Specify registration number of the patient(s) maintained in Form No. 3-E and quantity dispensed to each	:	
5.	Closing stock	:	

Full Name/Designation (if any) : Signature of the overall in charge :

Note:
 (1) This record shall be maintained on day to day basis and entries shall be made for each day.
 (2) Entries shall be completed for each day before the close of the day.
 (3) The pages of the register shall be serially numbered.
 (4) Separate record shall be maintained for each essential narcotic drug.
 (5) This record shall be retained for two years from the date of last entry.
 (6) This record shall be produced before the concerned authorised officers whenever called upon during the course of their inspection/investigation.

Section 52r it covers the duties of registered medical practitioner and maintain following records for 2 years.

Now, patient record is maintained in form 3e, recipient disbursement record is maintained in form 3h. So, we can see this is form 3e and this is form 3h.

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Sec 52-R: Duties of registered medical practitioner
 File Return before **31st March in Form 3I**
Sec 52-T: Next Year's Estimate by 30th November in Form 3J
 In case the requirement **exceeds** the Annual Estimate then revised estimate to be given before 31st August of same year with brief justification while filing return in Form 3I.



FORM No. 3-J
 [See Rule 52-T(1)]
Estimate of Annual Requirement of Essential Narcotic Drugs

Return for the year : Date of submitting estimate :

1.	Number and date of the current certificate of recognition	:			
2.	Name of the Recognized Medical Institution	:			
3.	Details of the estimated annual requirement of essential narcotic drugs	:			
Sl. No.	Name of the essential narcotic drug	Quantity disbursed during previous year	Estimated annual requirement	Revised estimated annual requirement*	Reason for revision
(1)	(2)	(3)	(4)	(5)	(6)

* Please attach copy of the original estimate
 Full Name/Designation (if any) : Signature of the overall in charge :

FORM No. 3-I
 [See Rule 52-R(1)(d)]
Annual Return of Procurement/Disbursement of Essential Narcotic Drugs
 (To be filed by Recognized Medical Institution)

Return for the year : Date of submitting return :

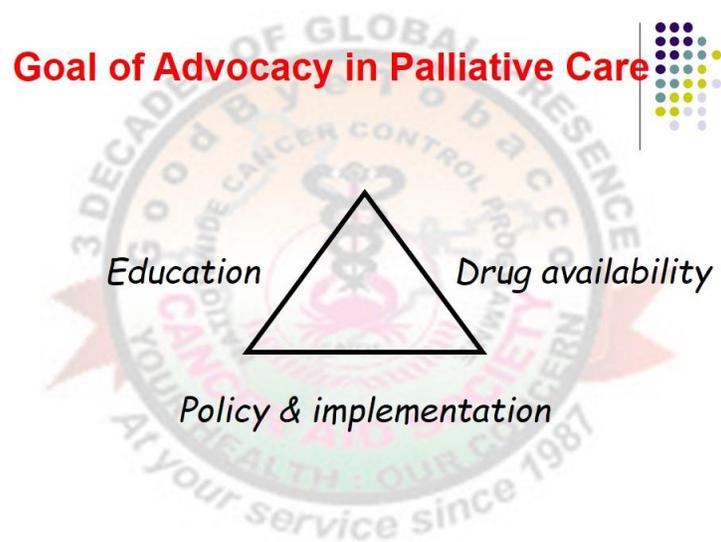
1.	Number and date of the current certificate of recognition	:					
2.	Name of the Recognized Medical Institution	:					
Sl. No.	Name of essential narcotic drug	Quantity in original annual estimate	Quantity in revised annual estimate (if any)	Opening stock	Quantity procured during the year	Quantity disbursed to patients during the year*	Closing stock
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

* The designated medical practitioner or the over-all in charge, as the case may be, shall record a brief justification where the actual disbursement is more than ten per cent of the estimate or revised estimate, as the case may be.
 Full Name/Designation (if any) : Signature of the overall in charge :

Now, section 52 r explains about the duties of registered medical practitioner and he has to file return before 31st of March in form 3i. Section 52t this covers about the next year's estimate by 30th of November in form 3j it has to be submitted. And in case the requirement exceeds the annual estimate then revised estimate to be given before 31st of August of the same year with brief justification why it has to be increased and it has to be filed in return form 3i.

So, here we can see the extracts of form 3j and form 3i where you are asking for increased demand for oral morphine and other essential narcotic drugs.

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So, what is basically goal of advocacy in palliative care? So, one thing is education which already you are into. Next part is that after getting educated how you are going to use essential narcotic drug especially oral morphine. Now, availability of oral morphine is very important and for this you have to sensitize the government officials regarding the amended NDPS act 2015 because right now it is not being followed and implemented. So, you will help in implementation.

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Take home message



- Concept of total Pain as whole family suffers
- Oral morphine is mainstay of Cancer Pain Management but advocacy is required for its availability.
- Licensing for Essential Narcotic Drugs is now given by Drug Controller in all the States to Recognized Medical Institutions.
- Government Hospital are deemed as Recognized Medical Institution.

What is the take home message? Concept of total pain as whole family suffers not only the patient itself. Oral morphine is mainstay of cancer pain management, but advocacy is required for its availability because you will not find it available easily in all across the country other than Kerala. Licensing for essential narcotic drugs is now given by drug controller in all the states to the recognized medical institutions. Government hospitals are deemed as recognized medical institutions. That means, they have to be given licenses without following the conditions of RMI, but again all record keeping and all other procedures after licensing has to be done by all the government hospitals.

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Cancer Aid Society



Is an ISO 9001 NGO having:

- Special Consultative Status with the United Nations Economic and Social Council
- Associate Department of Global Communications United Nations
- Member of World Health Organisation's Global Coordination Mechanism for Non Communicable Diseases
- Winner of Best NGO, Best NGO in Health Care, Best Cancer Awareness NGO and several Awards.

So, cancer aid society is an ISO 9001 NGO having special consultative status with United Nations Economic and Social Council.

We are working in association with department of global communications of United Nations. We are member of world health organizations, global coordination mechanism for non communicable diseases and we have several awards to our credit like best NGO, best NGO in health care, best cancer awareness NGO etcetera.

Thank you. Have a great day ahead.