

Basic Certificate in Palliative Care
Dr. Geeta Joshi
Dr. Piyush Gupta
Dr. Col. Yashavant Joshi
International Institute of Distance Learning
Indian Institute of Technology, Kanpur

Week-12
Lecture 02: Availability of ENDS and Advocacy

This is week number 12, lecture number 2. Namaste (Hindi word meaning greetings), I am going to talk about availability of essential narcotic drugs in India. As we learnt in previous weeks that essential narcotic drugs are important drugs required for palliative care patient particularly cancer pain patients who are having moderate to severe pain and which can be treated only by narcotic drugs like morphine, fentanyl, methadone etcetera.

*AMONG THE REMEDIES WHICH IT HAS PLEASED
ALMIGHTY GOD TO GIVE TO MAN TO RELIEVE HIS SUFFERINGS,
NONE IS SO UNIVERSAL AND
SO EFFICACIOUS AS OPIUM*

-- THOMAS SYDENHAM ,ENGLISH SCIENTIST



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Among the remedies which it has pleased almighty god to give to the man to relieve his sufferings none is so universal and so efficacious as opium. So, Thomas Sydenham has said that opium is such a drug which is the boon to human mankind for relieving his suffering.

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Morphine

**Controlled Release morphine
Is **GOLD STANDARD** of Rx**

Around the  No upper limit
clock Of the dose

**Few patients need
> 200 to 300 mg**

There is no difference in efficacy between oral tabs, rectal suppositories
& parenteral injection,
Between Controlled Release & Immediate Release morphine

We also studied that morphine is a gold standard of treatment for cancer pain and because it does not have any upper limit of the dose you can increase the dose as long as pain is not relieved.

You can give it around the clock and many fewer patients needs more than 300, 400 milligram of morphine per day and that we can give them safely. There is no difference in efficacy between the oral tablet it the mechanism of action or efficacy of action is same even if the when the drug is given by oral route by rectal suppository or by parenteral injections and even immediate release tablet and control release tablet has got similar efficacy. So, that is the beauty of morphine tablet oral morphine which is given to the palliative care patients.

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EVIDENCE : Morphine

Sawe S et al.....

Studied pharmacokinetics Of
high dose of morphine

Long term Rx with 10 to 20 fold
Increase of oral dose over a period of
6 - 8 mths doesn't change kinetic of morphine

Clinical Experience.....

- ⊗ Physical dependence & tolerance
- ⊗ This doesn't prevent the effective use
- ⊗ Addiction & Respiratory depression
are rare in cancer patients



This study shows that even if the large dose of opium morphine is given for a very long time 6 to 8 months to patients and they studied the pharmacokinetic of the drug and they found that there is no change in pharmacokinetic of the drug.

So, the three is not the morphine is such a drug when given orally the patient does not develop tolerance. So, you can give large amount of drug for a very long time to these patients.

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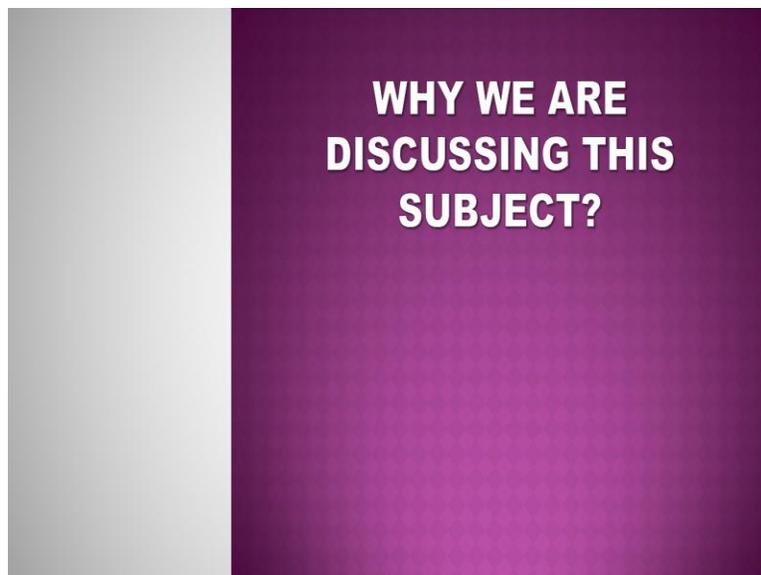
History : Opium, The double edged weapon!!!

- In the sixteenth century, laudanum, opium prepared in an alcoholic solution, was used as a painkiller
- In 1950s, The term "**opioid**" originated
Opioid - from Opium
Opiates - Morphine & similar substances derived from Opium
- By the 1800s, physicians were using morphine in its pure form
In 1803, morphine was discovered and named after Morpheus, the Greek God of Dreams.
- 1850s and 1860s smoking opium by Chinese laborers
In 1853, hypodermic needles were invented
Morphine was used American Civil War as an injectable pain reliever, leading to the first wave of morphine addiction

So, in coming to history of opium in 16th century laudanum that is opium prepared in a alcoholic solution and was used as a pain killer. The term opium was originated in 1950s and opiate means morphine and similar substances. In 1800 physicians were using morphine in its pure form.

So, in 1803 morphine was discovered and was named after the morpheus the Greek god of dreams. In 1850s and 60s Chinese labourers used to use morphine in smoking form smoking morphine and in 1853 hypodermic needles were invented and thus first time morphine was used as a pain killer in American war, civil war. So, this is the time when the soldiers become addicted to morphine and this property of morphine became prominent and was discovered during the American civil war.

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Why we are discussing this subject of availability of morphine? Like other drugs like paracetamol or like tramadol or like any other drugs they are easily available, but why there is so much of talk and discussion and advocacy taken up for the availability of the morphine.

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Unrelieved Pain

Predictors and Prevalence of Pain and Its Management in Four Regional Cancer Hospitals in India

Journal of Global Oncology 2017

In this study,

- Nearly nine of every 10 patients (88%) in four regional cancer centers in India reported pain.
- Two thirds (67%) of these patients received inadequate pain management.
- In-patients and newly registered outpatients reported similar levels of severe pain (57% and 63%, respectively),
- Newly registered outpatients were more likely to have pain relief inadequately
- managed pain (81% v 54% for inpatients), which suggests a failure of secondary referral hospitals in the provision of adequate pain treatment.

Coming to this study that there is lots of unrelieved pain in our patients. This study was taken up in four regional cancer centers in 2017 and as per this study it was found that 99 of nearly 9 of every 10 patients in four regional cancer center in India reported pain. Whenever they came to hospital almost 9 out of 10 patient reported pain means their pain was not treated and two-third of this patient had inadequate pain management outside when, when they come for the first time to hospice. Even indoor patients who were admitted in the ward in this population also almost 57 to 63 percent of the patient had earned severe pain reported during evening or night time. This shows that even when patient is admitted to hospice they do not have effective pain management. Newly registered outdoor patient were more likely to have pain and inadequately treated. So, this shows that we pain is not attended properly, pain is not managed properly and patient has inadequate pain management.

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Pain Prevalence & Need of Opioids

80% of Cancer patients
&
50% of HIV/AIDS
patients have
Moderate to severe pain,
which needs to be treated by opioids



More than half of all hospitalized patients experienced pain in the last days of their lives and although therapies are present to alleviate most pain for those dying of cancer, research shows that 50-75% of patients die in moderate to severe pain.

Source: A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients.
JAMA

Pain prevalence is shown in this slide. Most in cancer patient 80 percent of the cancer patient has moderate to severe pain and 50 percent of the HIV AIDS patient has moderate to severe pain and these are the patient who needs opioids or morphine for their pain management. And more than half of all hospitalized patients experience pain in last days of their life. So, it was reported that almost 75 to 50 to 75 percent patient die in moderate to severe pain means their pain was not attended.

So, what is wrong? Why the pain was not attended? There are many factors responsible for this and one of the factor is availability of the essential narcotic drugs and that is what we are going to address in this lecture.

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Morphine Consumption of a Country

Researchers historically have used these consumption statistics as a proxy for medical use and as an indication of the capacity of a country to effectively treat moderate to severe pain.

WHO historically has considered a country's annual consumption of morphine as an indicator of the extent that opioids are used to treat moderate to severe cancer pain, as well as an index to evaluate improvements in pain management

It is calculated as Morphine Consumption Mg per capita

$$\text{Per Capita} = \frac{\text{Total amount of opioid consumed in Kg}}{\text{Population of country for that year}}$$

How this access or availability of morphine is measured for a particular country? It is measured by morphine consumption of a country. So, researchers historically have used this consumption statistics and as a proxy for medical use and as a indication of the capacity of a country to effectively treat moderate to severe pain.

Morphine consumption is a indicator that whether this country is effectively treating moderate to severe pain or not. Secondly, WHO historically has considered a country's annual consumption of morphine as a indicator of the extent that opioids are used to treat moderate to severe cancer pain as well as an index to evaluate improvement in pain management. This is also a index to evaluate that this country is effectively managing pain and there is a improve in pain management particularly moderate to severe pain management.

How the morphine consumption is calculated? It is per capita consumption is calculated by total amount of opioid consumed in kg divided by population of the country for that year. So, as per this the International Narcotic Bureau finds out the morphine consumption on each and every country and it is listed down like this.

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Global Morphine Consumption, 2007: mg/capita

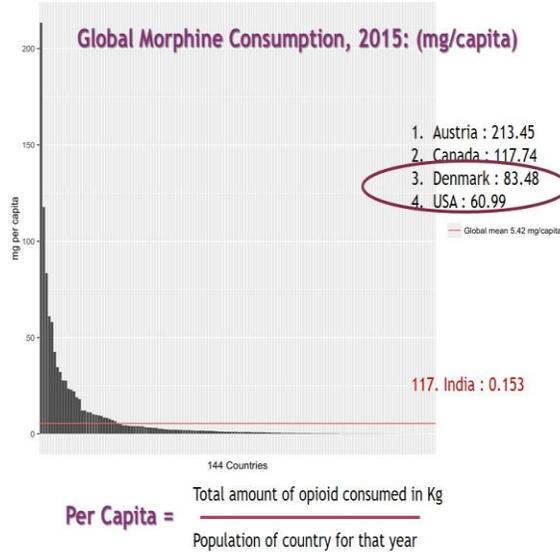
Note: Countries not listed did not report morphine consumption to the INCB for 2007

1	Austria*	153.4793	55	Armenia	1.4263	108	Turks and Caicos Islands	0.1515
2	United States of America	76.7854	56	Macao	1.4138	109	Ecuador	0.1501
3	Canada	71.1903	57	Georgia	1.4082	110	Cape Verde	0.1460
4	Denmark	54.3233	58	Trinidad and Tobago	1.3315	111	Turkmenistan	0.1438
5	Portugal	53.3458	59	St Vincent and the Grenadines	1.3300	112	Egypt	0.1299
6	Australia					113	Panama	0.1159
7	Iceland					114	Uzbekistan	0.1117
8	France					115	Brunei	0.1100
9	Switzerland					116	Kyrgyzstan	0.1100
10	Norway					117	Montenegro	0.0993
11	Slovenia					118	Nicaragua	0.0994
12	Germany					119	Paraguay	0.0952
13	Netherlands					120	Guatemala	0.0809
14	United Kingdom					121	Senegal	0.0760
15	New Zealand					122	Algeria	0.0670
16	Sweden					123	Azerbaijan	0.0663
17	Falkland Islands					124	Maldives	0.0633
18	Belgium					125	Macedonia (FYR)	0.0610
19	Gibraltar	12.4075	73	Oman	0.7400	126	Dominica	0.0600
20	Malta	11.7500	74	Suriname	0.7040	127	Ghana	0.0497
21	Argentina	11.5960	75	Tonga	0.6500	128	Indonesia	0.0439
22	Ireland	9.4083	76	Qatar	0.6388	129	Finland	0.0353
23	New Caledonia	9.4478	77	India	0.6103	130	Pakistan	0.0339

**India used Morphine
120 Kg / Yr
Against
900 Kg / Yr**

So, in as per 2007 data India was to consume 900 kg of morphine against this India had the morphine consumption was only 120 kg per year. So, there is a huge gap between the morphine consumption required against the morphine consumption happened in in real sense. The countries which are topping the, so India stands at number 77, the countries which are topping the list are Austria, United State of America in 2007. So, the country who has got less population has got more morphine consumption and countries who has got more population more number of cancer patient has got less morphine consumption. So, this is imbalance and this suggest that countries which are consuming huge amount of morphine they there is because of because there is a misuse of the morphine and abuse of the morphine in this countries.

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In 2015 USA was in 2007 it was at second place it came down to number 4, because they also realize that they have to have some balance between the real morphine consumption required and the against the abuse of the morphine.

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Under Pressure: The Tension Between Access and Abuse of Opioids in Cancer Pain Management



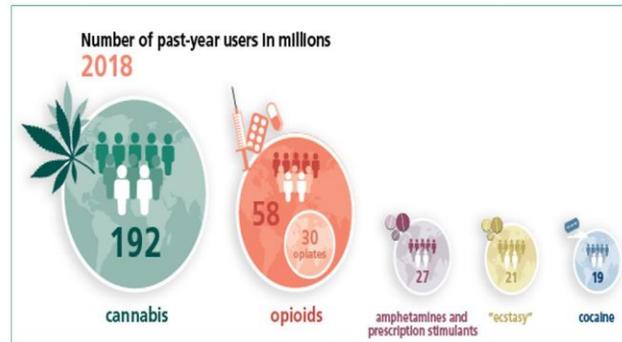
Judith A. Poice J of Oncology Practice 2017;13;09;595-6

- ✓ Production quotas for opioids for 2017 **reduced by 25%**
- ✓ Limited access to opioids for patients with cancer pain
(No longer prescription, failure to get it filled, limited stock
Not covered under insurance, documentation for authorization)
- ✓ Great uncertainty & tension in society & health care, the Balance shifting away from the needs of patients with cancer Related pain.

So, they also became strict with their medical professionals regarding and tried their best to prevent the abuse of the morphine appears in cancer pain management. So, in America also they cut down the production by 25 percent, limited access to appeared for patient

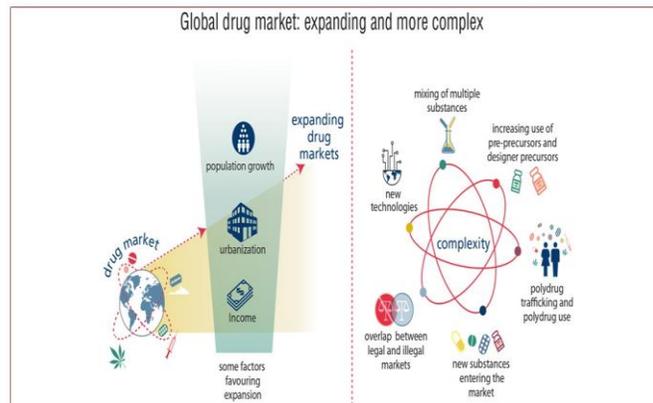
with cancer pain. So, no long longer prescription patients are not given prescription of more than 15-20 days previously they used to give for 1 month and 1 and half month. Then whenever they get for refilling of the prescription they will check everything documentation limited stock is given and not it is not covered under insurance and documents are submitted for the proper authority. So, this is the way countries which are consuming more morphine they are also having stringent rule to to have a check on the abuse of the opiod consumption.

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These are the number of past years users in millions in 2018 cannabis users when 192 million, opioid users were 58 millions, amphetamines and other drugs users went 27, ecstasy users were 25 and cocaine users were 95, 19.

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Now global drug market also becoming very complex because of expanding in the drug expansion of the drug market because of the increase in income urbanization and population growth there is a steady increase in drug market and there is a increase in drug consumption. Secondly because of the technology newer combination of the opioid drugs are in market nowadays and which are which are abused by the drug users.

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UNMET NEED FOR PAIN RELIEF

96% adults and 99% children who require opioids DO NOT have access to it.

28 January 2014 | GENEVA/LONDON

Only 1 in 10 people who need palliative care - that is medical care to relieve the pain, symptoms and stress of serious illness - is currently receiving it

1/6th of world's population



Unbearable Pain ... Human Rights Watch report - 2010
 Duthey B, Scholten W: J of Pain and Symptom management 2013
<http://www.nacoonline.org/QuickLinks/HIVData>

We are discussing this topic because there is a huge unmet need for pain relief 96 percent adult and 99 percent children who require opioid do not have access to it and only 1 in 10 people who need palliative care that is medical care to relieve the pain symptoms and stress of serious illness is currently receiving it.

So, because of all these reasons it is very important for all palliative care physician to understand the morphine availability how it is procured and what is NDPS act.

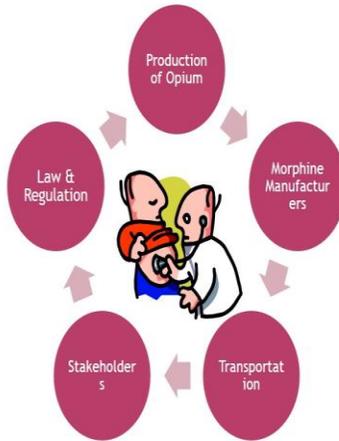
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So, why there is a issue of availability of opioids? What are the issues that you are going to discuss in following slides?

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Who are involved in making Morphine Available to patients?



In morphine availability the number of people are involved first is production of opium again it is it should be after proper licensing from a authority and it is it cannot be taken up by anyone without license. Then morphine goes to manufacturer for the medical morphine manufacturing unit then it is transported and comes to the dealers chemist stakeholders various stakeholder at various stage has a big role to play and this whole process is governed by law and regulation. So, because of so many steps and so many stakeholders are involved in making the morphine available to our patients and how these things makes the thing very complicated that we will see in next slide.

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Opium Production

Central Bureau of Narcotics
is responsible for overall
supervision of cultivation

India is the only licit supplier
of opium to the world market,
(America, Iran, Japan, Other countries)
and most of the opium produced in India
is destined for export



(Rajasthan, MP & UP)

First of all opium production it is done opium is cultivated in Rajasthan, Madhya Pradesh and Uttar Pradesh. It is governed by central bureau of narcotic which is responsible authority for overall supervision of this cultivation. India is the only licit supplier of opium to the world market. India has got huge production of opium, but the whole opium is exported and we our own patient does not have access to it. So, India supplies opium to America, Iran, Japan and other countries and most of the opium produce in India is destined to export.

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Manufacturing Morphine in India

Two National Competent Authorities for different aspects of narcotics control

- Narcotics Control Bureau (NCB) Ministry of Home Affairs**
 - Coordinating action among other drug law enforcement agencies
- Central Bureau of Narcotics (CBN) Department of Revenue, MO Finance**
 - Allots the estimates received from International Narcotics Control Bureau as quotas to manufacturing companies in the country
- Prohibition & Excise: Narcotic Commissioner issues license for manufacturers.**

Morphine Sulphate	Secondary, Tertiary levels	Injection	10 mg/ml
		Tablets	10 mg
Tramadol	Secondary, Tertiary levels	Capsules	50 mg, 100mg
		Injection	50 mg/ml
Fentanyl	Secondary, Tertiary levels	Injection	50 ug/ml 2 ml ampoule

National List of Essential Medicines

Coming to manufacturing of morphine after the opium is produced in opium field it is gathered from there and goes to the factory for the production of medical morphine. There is a national list of essential medicine and this list has got morphine, tramadol and fentanyl on its list means all health at least tertiary healthcare center should have this drug available in their premises.

In spite of that may most of our healthcare system does not have morphine available in their pharmacy. Why? Two national competent authority for different aspects of narcotic control. So, narcotic control bureau of which is under the ministry of home affair it coordinates the action among other drug law enforcement agency. Then there is a central bureau of narcotic under the department of revenue and ministry of finance which allows the estimate really received from the international narcotic control bureau as a quota for manufacturing company in the country. So, central bureau of narcotic gives license to a company to manufacture this much quota of morphine.

So, that is one authority. Third authority which comes into the picture is when this drug is given to a institute or a doctor. Here the licensing authority is prohibition and excise or narcotic commissioner which issues the license for the manufacturer as well as for the chemist to stock the morphine. So, so many departments and so many authorities are involved in manufacturing of the morphine, transporting to the chemist from chemist to the institution.

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Preparations of Essential Narcotic Drugs (ENDs) in India

Morphine

- Tab - 5, 10, 20, 30, 60 mgs IR & SR
- Solution 1mg/ml (Kidwai Memorial)
- Injection 10 or 15 mg/ml

Fentanyl

- Injection - 100 ug
- OTFC - 200 ug
- TTS - 12, 25, 50 ug/Hour

Methadone

- Tab 5mg
- Syrup 5mg / ml

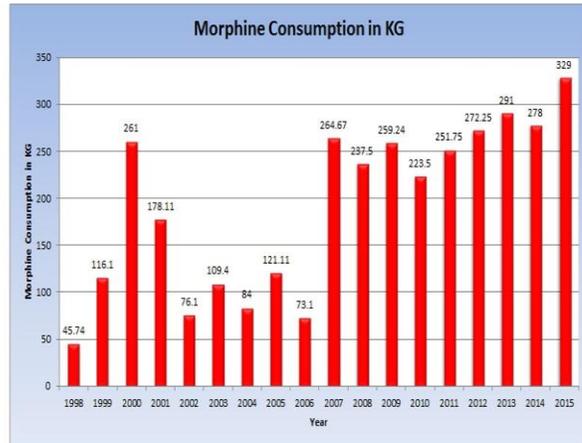
26
Manufacturers;
most make
only injections

The common preparations which are available in India of the essential narcotic drugs are tablet morphine, injection morphine and solution morphine that is oral solution which is available only in Kidwai Memorial Hospital Bangalore.

They get a powder morphine from Ghaziabad and then they prepare oral solution in their own pharmacy and patients are given solution in bottle bottles. Rest of all institution has got tablet morphine in their pharmacy institution which has got license to stock the morphine. Fentanyl is available in form of injection, OTFC that is a lollipop, transdermal therapeutic system that is patch etcetera. Methadone again it is available in India recently since last 3 or 5 years and it is available in syrup form.

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Quantity of morphine sent out from Govt opium & alkaloid factory



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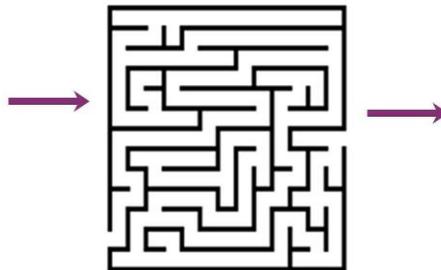
This slide shows people realize the importance of morphine and quantity of morphine sent out from government opium and alcohol factory up to 2015 this is a very old data.

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Transport of Morphine

Department of Prohibition & Excise

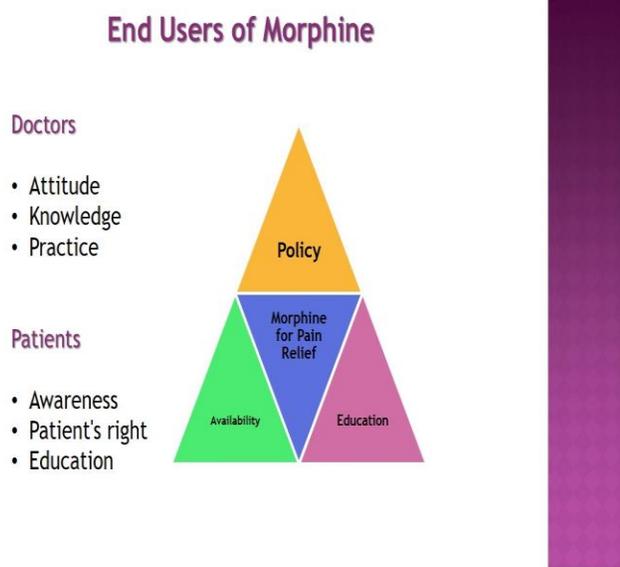
- Issue License to Chemists, Dealers, Organisation
- Inter-state Transport Permit (import & Export)
- Road Permit



So finally, after cultivation, after manufacturing and after coming to chemist the role of prohibition and excise comes into the picture. So, prohibition and excise is one authority which gives license to the chemist and druggist for procurement of the morphine. It is the also authority to give license to the institution and doctors to buy morphine to purchase

morphine from the chemist. So, the whole and all this thing requires many licenses in between like transporting the morphine from chemist to institution it requires road permit. Suppose the manufacturer is outside the your state suppose I am in Gujarat and I want morphine and the manufacturers is in Madhya Pradesh, then they need interstate transport permit to send the morphine from Madhya Pradesh to Gujarat. So, this because of this the whole scenario of transportation and procurement of morphine is a maze like structure and very complicated.

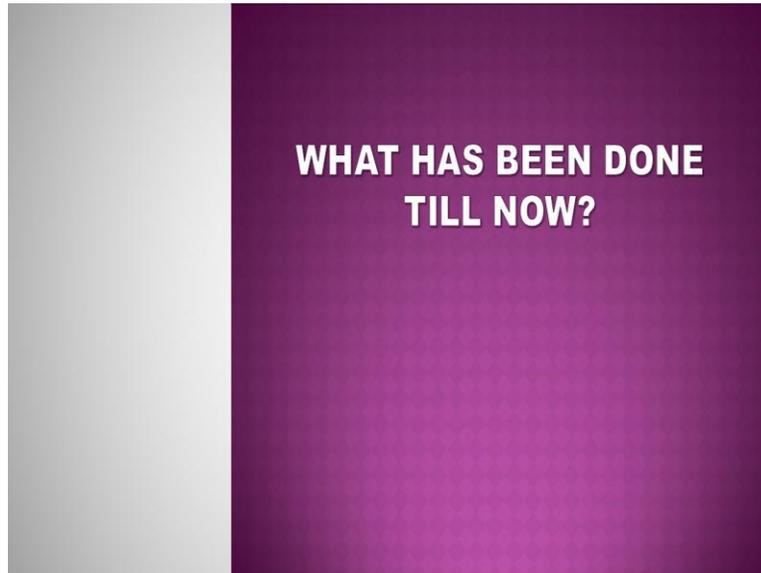
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On above all this factor again very few many factors at the end of doctor and patient also contributes and makes morphine unavailable for the pain management. The factors which are responsible on doctor side is their attitude, their myth about handling morphine, their knowledge about handling morphine and their practice about prescribing morphine for the pain management. This all things requires a particular training and practical exposure to the doctors. Secondly, patients are also not aware that it is their right to get their pain relieved.

So, their awareness is not there and a patients are not educated. So, education, availability, policy if all these things combined properly then also only the morphine can be made available for the pain management of our cancer patients.

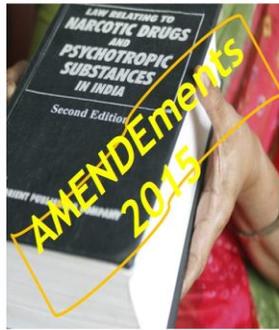
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And see so far we saw the scenario is very gleam and we feel that it is very complicated morphine cannot make be available for the patient, one should not prescribe morphine, we can do without morphine and all such thing, but no it is not so. Many many attempts efforts has been done in last 5, 15 years, but it is not so. To make this scenario less complicated to make the morphine available to our patients.

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NDPS Rules Declared in May 2015



This amendment aims at broadening the scope of the Rules to include access and availability of opioids for medical and scientific use.

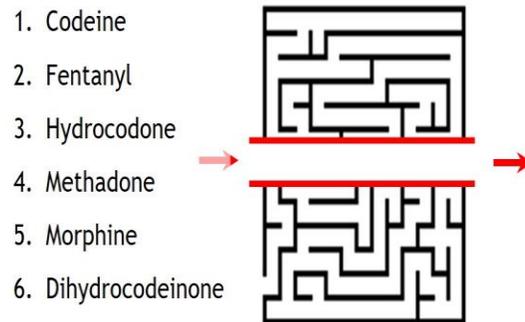
Govt - IAPC - Pallium India - WHO - NGOs

So, here we will see what has been done. As per NDPS, NDPS rule were declared in May 2015. The NDPS act was amended in 2015 and this time the amendment was, the focus of this amendment was to make morphine available for the medical and scientific use. The NDPS act was enacted in 1985 that time it was so stringent that the main aim was to prevent the drug trafficking, prevent its misuse and all such thing. And because of this stringent rule even medical doctors were afraid of using morphine for pain management, but lots of efforts had been put by government of India, Indian association of palliative care, Pallium India, WHO and various NGOs who are involved in palliative care in advocacy of for palliative care.

They made lots of effort and the rules were amended in 2015. So, the now it has become a clear road to get the morphine for your patient.

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NDPS amendment for Essential Narcotic Drugs (ENDs)



So, what amendment has done? As per NDPS amendment act 2015, they identified 6 essential narcotic drugs. These 6 drugs essential narcotic drugs are coden, fentanyl, hydrocodone, methadone, morphine and dihydrocodone. For these 6 drug the rule is simplified.

All states various states in India had various rules their own rules about the morphine availability. But now all state has to follow this rule for particularly for these 6 drugs. So, there is a central rule, uniform rule and all state has to follow this rule for availability of ENDs essential narcotic drug. So, it is a instead of maze like structure it is a straight road and if you travel on this you will be able to get morphine for your patients.

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What NDPS Rules 2015 mean?

Essential Narcotic Drugs: Central rule for all ENDs

Registered Medical Institutions: Govt hospitals will be deemed as RMIs, License by Food & Drug Controller Authority

Registered Medical Practitioner: MBBS, BDS who has Undergone training in Pain & Palliative Care Or Opioid Substitution Therapy (OST) can prescribe ENDs

Role of Drug Controller: will be licensing authority for RMIs and RMPs

Proper documentation to avoid abuse of opioids

So, what happened in this amendment? Firstly, they identified in this amendment 6 essential narcotic drugs were listed and which which are governed by central rule.

Secondly, they identify they said that in this rule it has been stated that registered medical institutions either it may be government institution or other institution can be deemed as RMI, can be given a recognition as registered medical institution and a, and their license licensing process will be taken up by food and drug control authority we call it FDCA. So, now, prohibition and excise is not in picture for licensing of this registered medical institution. So, so the whole licensing process is divided into licensing of chemist and druggist is done by prohibition and excise and licensing of a registered medical institution and registered medical practitioner means doctors is done by FDCA food and drug control authority. They also defined registered medical practitioner. Who are registered medical practitioners? They are MBBS or BDS doctors and who has taken a training in pain and palliative care or a training in opioid substitution therapy. So, that they can govern the whole procurement and prescriptions, talking and everything about the ENDs.

So, all and again licensing authority for these doctors registered medical practitioners are food and drug controller authority. So, it has been now stated in this rule that all RMI should have one RMP, one doctor who is trained in pain and palliative care who should be a MBBS or BDS doctor and he should be overall in charge of procurement, stocking,

dispensing, documentation, licensing, getting license and all such thing he will look after. So, because of that institutions are encouraged to procure morphine. If a big institutions or any small institution has got morphine the number of patients treated in these institutions are very large and more and more patient will have access to morphine. So, role of drug controller has come in picture in this amendment where he will become a licensing authority he has become a licensing authority for RMI and RMPs. Under this amendment proper documentation is also given, has been defined and this will be given to the patient. So, he will avoid the abuse of the opioids.

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How NDPS 2015 can improve access to Opioids?

- ✓ Licensing to RMI is simplified, hence Opioid can be made Available up to district hospital level under National Program for Palliative Care
- ✓ RMPs role has been defined
- ✓ Documentation simplified
- ✓ Demand, increase in quota etc simplified

What is the confusion?

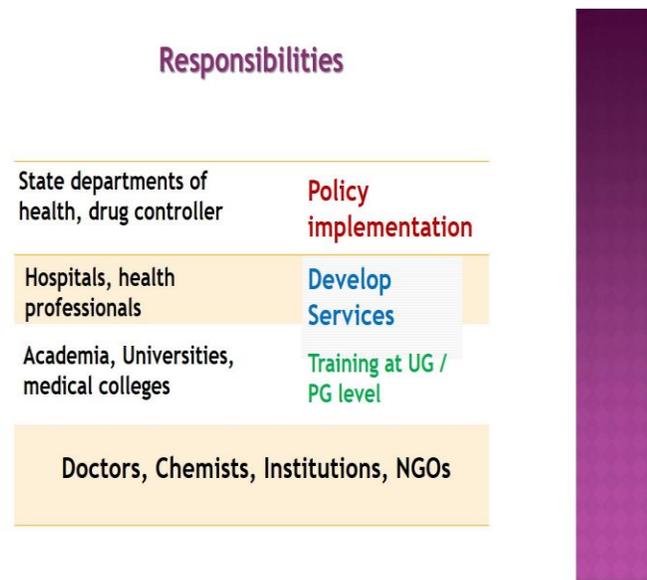
- ✗ Only 13 states have simplified rules & implemented amendments
- ✗ Training of RMP - Who? Syllabus? Centers?
(Now this has been defined as 3 days "Hands on" training in Palliative Care centers)
- ✗ How chemist will identify the trained RMPs?
- ✗ How to train such a huge number of physicians?
- ✗ No change in punishment

So, how NDPS 2015 can improve access to opioid because licensing to RMI is simplified. Now, government hospitals are deemed RMI they can straight away apply for the license or apply for the quota they of morphine they want and then they will be given license. Other institution has to just apply for the license, but not licensing authorities, FDCA, drug controller.

So, it is much simplified than the prohibition and excise department. So, licenses is simplified more and more RMI will come up and they will stock morphine they will get license and then more and more number of patients will access to morphine. RMPs role has been defined each institution will have one RMP or if it is more than one RMP there

will be one RMP designated medical practitioner who will be responsible for licensing, stocking, purchasing of the morphine, dispensing of the morphine, keeping the records and everything. So, because of all this now it has become very easy for any institution or any doctor to have license of the narcotic, essential narcotic drugs and which they can prescribe to their patients.

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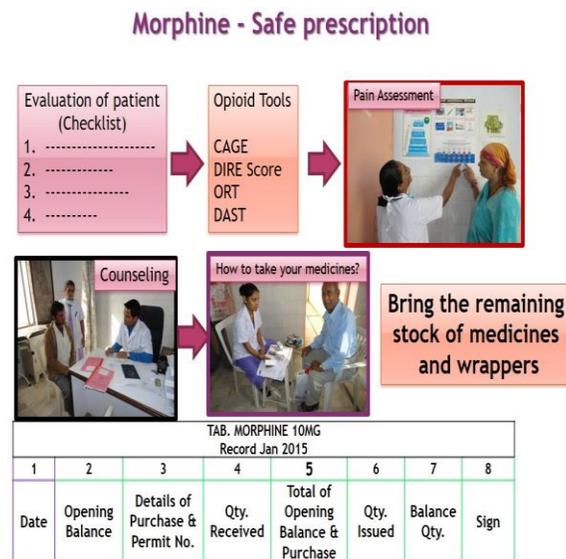


So, it is not only the responsibility of one authority to have morphine available in the in their in their hospital or in their clinics, but several departments plays a very important role like state department of health and drug controller, policy they will they they are responsible for implementing the policy of licensing and purchasing documentation and all such thing.

Hospitals health and professionals they should develop the services of pain clinics, palliative care clinics. So, that patient's can identified who are in need of opioids or essential narcotic drug and they can have enough quota available for the pain management of this patient.

Role of academic institution university and medical colleges is to train undergraduate and postgraduate in the subject of palliative care, pain management, use of oral morphine etcetera. So, it is a combined responsibility of doctors, chemist, institution and NGOs to make morphine available in their own setup and give it make it available for the patient for pain management. This is the in brief about the NDPS act 2015 which was amended in 2015 to make morphine available in our institution through simplified narcotic law.

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Again this we already discussed in our previous lectures that it is also responsibility of all this authority administrator, doctor, paramedical staff to make morphine prescription as safe as possible. And this can be done by forming a guideline in your department, forming a guideline in your institution or forming a guideline in your clinics wherever you are treating pain patients. It starts with evaluation of the patient there is a always checklist, then evaluating the patient that whether he is likely to misuse of the misuse the morphine by using the opioid tools, assessing the pain, counseling of the patient and how to take medicine, how to take the morphine tablet all this should be properly taught to the patient and caregiver. So, proper communication, counseling and education of the patient and caregiver before giving morphine is very very essential.

In pharmacy this is the way the record is kept on particular date what was the opening balance of the morphine tablets, any number of morphine added because of the new purchase then total quantity received. So, that will give you the total opening balance and purchase then at the end of the day total number of morphine tablet given to the patient and what is the balance quantity and then signature of the person who is overall in charge of this morphine handling of the morphine. So, this is the way you have to keep the documents ready. A FDCA inspector or a drug controller may visit your clinic or your institution to check whether you are keeping proper documents or not and whether your stock of the morphine is as per the documents available or not.

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How to calculate Morphine requirement of your institution?

	Deaths per year	% with Mod to severe pain	No of deaths with mod to severe pain
Cancer	1000	80%	800
HIV	500	50%	250
Total			1050

Morphine Requirement = 70mg / day = 1050 X 70
= 73500 mg / day = 73 gm / day = 2190 gm / month

Include all opioids by calculating their Morphine equivalents
e.g. 25 mcg Fentanyl = 60 mg Morphine
20 mg Methadone = 80 mg morphine

How to calculate morphine requirement of your institution? Because when you are applying for the license you have to apply for certain quota of morphine that how much morphine you will use in 1 year for treating your patients. So, how you will find out this quota? This depends on how many number of cancer patients you are treating or whether you are treating HIV and AIDS patient. If you are treating cancer patient and HIV patients you find out number of death per year suppose in cancer patient about 1000 patient died last year in your hospital and HIV patient suppose 500 patient died of HIV last year in your hospital. Out of these 80 percent of the cancer patient will need morphine and 50 percent of the patient's cancer patient will need morphine and 50

percent of the HIV patient will need morphine. That means, last year out of your total patients in your hospital 800 cancer patient and 250 HIV patient needed morphine.

That means, 1005, 1050 patient needed morphine. Now, 1 person patient who has moderate to severe pain will need on an average 70 milligram of morphine per day. So, morphine requirement is 70 milligram per day is equal to 1050 into 70 that is 73 milligram per day and it will come to 2190 gram per month. So, this is the quota you need and you multiplied by 12 for a yearly requirement and that quota you submit to the drug controller when you are asking for license. Suppose out of this quota 2190 gram per month you need small portion as a fentanyl patch and a small portion as a methadone then there is a conversion table that 60 milligram per day. So, 600 milligram of morphine is equal to 25 microgram of fentanyl.

So, suppose you want 10 patches of fentanyl you convert this way 60 into 10 about 600 milligram of morphine out of this 600 milligram morphine in form of patch and methadone is 20 milligram methadone is equal to 80 milligram of morphine. So, suppose you want 10 one bottle of methadone contains 750 ml. So, you calculate accordingly and 1 ml contains 5 milligram of methadone. So, that way you calculate and ask for that much amount of cut down that much amount from this total and you ask for methadone. So, this is the way you can procure license for END's license for morphine license for methadone license for fentanyl or you can all are taken up separately and their requirement also can be calculated like this.

I hope I have simplified this very complicated subject, but still it requires repeated reading and maybe some reading from the internet. One thing which you must practice is always balance opioid use of opioid to reduce suffering against the use of opioids for misuse. So, safe use of morphine is your own responsibility and it is the one where you can achieve this balance and be very useful to your patients and society.

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They need Morphine for better living!!!



These are the photographs of the patients who, who are in moderate to severe pain and they really need morphine. Thank you very much.