Narcotic Drugs and Psychotropic Substance usage in Hospital as per the NDPS Act

Presented By:

Ms. Amreen Shaikh

Ms. Christy Sam Varghese

Ms. Gauri Patel

Dr. Nilesh Singh

Reviwed By:

Dr.Lallu Joseph

Dr.Saravana

Dr.Anil

Narcotics Drug Management

Narcotics are drug that produces analgesia (pain relief), narcosis (state of stupor or sleep), and addiction (physical dependence on the drug).

They are also known as opioids.

Important Terminology in the NDPS Regulations.

- Medical Institution

Hospital, dispensary, clinic or institution that offers services or facilities requiring diagnosis, treatment or care of illness, disease, injury, deformity or abnormality, established, administered or maintained by the government or Municipal Corporation, Municipal Council or Zillah Parishad or any person or body of persons

- Recognized Medical Institution (RMI)

A medical institution, officially recognized by the State Drug Controller for purchasing, possessing and dispensing essential narcotic drugs for medical and scientific purposes.

- Essential Narcotic Drugs [END]

This refers to the list of 'notified' medicines which have been identified by the office of Drug Controller General of India, for medical use in an RMI.

- The Officer in charge (Pharmacist) of the RMI

Any person registered as medical practitioner or registered pharmacists registered as per the under law that is time being in force; and who has undergone training in the medical use of ENDs

Brief about NDPS Act, its provision and its amendment

- **Intent of the Act:**

To consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances [to provide for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, to implement the provisions of the International Convention on Narcotic Drugs and Psychotropic Substances]and for matters connected therewith

- **About the Act:**

The Narcotic Drugs and Psychotropic Substances Bill, 1985 was introduced in the Lok Sabha on 23 August 1985. It was passed by both the Houses of Parliament and it was assented by the President on 16 September 1985. It came into force on 14 November 1985 as THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, 1985 (shortened to NDPS Act).

- **Under the NDPS Act, it is illegal for a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, and/or consume any narcotic drug or psychotropic substance.**

- **Amendment of the Act**
  1988,
  2001,
  2014.
- **2014 Amendment - need for pain relief as an important obligation of the government.**
  It creates a class of medicines called Essential Narcotic Drugs (ENDs).
-
- Drugs Included in Act - 6 drugs namely
  a. Morphine,
  b. Fentanyl,
  c. Methadone,
  d. Oxycodone,
  e. Codeine and
  f. Hydrocodone.

And other various formulations

Basis for the NDPS Amendment 2014

- Opioids are safe, economical and effective for management of severe pain in selected groups of patients.
- There is Need to facilitate and improve access to opioids for medical use while maintaining, strengthening and integrating programs to control misuse and diversion.
- Uniform and simple procedures are required for procurement of opioids for medical use across the country
- The NDPS Rules pertaining to the Act are now applicable uniformly across India
- Power for legislation on ENDs has been shifted from the state governments to the central governments so that the whole country now can have a uniform law covering these medicines which are needed for pain relief.
- Subsequently, NDPS rules which would be applicable to all states and union territories has been announced by the government of India in May 2015.

A Glimpse: The Amended NDPS Act 2014

- Expanded the scope of the Act to include Medical and Scientific Use
- Prepared a notified list of Essential Narcotic Drug [ENDs], i.e. the opioids identified for medical use, approved by the Drug Controller General of India.
- The notified list of ENDs currently includes -- Morphine, Methadone, Codeine, Hydrocodone, Oxycodone, and Fentanyl
- Transferred the power to regulate Essential Narcotic Drug [ENDs] to the Central Government.
- Regulations are applicable uniformity across India.
- It defined 'Recognized Medical Institutions' (RMIs) with criteria for stocking and dispensing opioids for medical use.
- Conferred the powers for authorizing medical institutions as RMIs, for stocking and dispensing ENDs, to a single state agency -- the State Drug Controller--SDC / Commissioner, Food & Drug Administration -- FDA
- Those Institutions fulfilling the criteria to be RMIs, may apply to the State Drug Controller--SDC / Commissioner, Food & Drug Administration -- FDA, to procure and dispense ENDs.
- The authorization of RMIs is for periods of 3 years, and renewable from the same agency. This removes the need for renewing multiple licenses from different government agencies every few months.

Responsibilities of RMIs

Institute/Hospital shall ensure and maintain the Minimum Mandatory Requirements as listed:

- The drugs shall be prescribed only by Registered Medical Practitioners
- Every RMI shall designate one or more RMP who shall be using essential narcotic drugs.
- Drugs shall be purchased only from authorized dealers. The list for the same should be available with the authorizing State agency. The list of licensed manufacturers would be available with the Narcotic Commissioner at the center.
- ENDs shall be prescribed as per the rules and dispensed only to selected patients, registered with the RMI.
- END stock with the RMI shall not be transferred, loaned or sold to other institutions except with the written permission of the Drugs Controller of the state.
- All records and registers shall be maintained as indicated in the Rules, for a period of two years from the last entry. They should be made available for inspection for the Commissioner of Food & Drugs Control Administration or any other officer authorized by him in this regard
- The expired stock of ENDs shall be destroyed in the presence of an official designated by the Hospital and the records for the same should be made available to the the State Drug Controller / Commissioner of Food & Drugs Control Administration.
- Unused ENDs returned by the patients, shall be considered as receipts, provided the drugs are not damaged or otherwise unacceptable for use.
- RMI shall submit the annual return [Form 3 I] before 31st of March every year even if they have not used any ENDs in the preceding year.

Licensing and Process of ENDS

- **Applying to the state drugs controller for RMI status:**

The application is sent in the format of Form no 3F to the State Drugs Controller/ FDA by the authority in--charge of the institution with details of the facility and with the name of the trained doctor who will be in--charge of the stocking and dispensing. The following documents are also required.

a. Covering letter stating the purpose

b. Filled application -- Form 3--F.

c. Completed Form 3--J which specifies the Annual Requirement of the ENDs and source(s) for purchase

d. Name of the employed doctor who would be the Officer in--charge and copy of her/his;

   - Medical graduation certificate
   - Certificate of registration
   - Certificate of training in medical use of opioids

e. Self --addressed stamped envelope [Stamp worth ₹ 27/--]

- **Inspection and authorization for RMI purpose**

The drugs controller / designated person will inspect the institution

If all the prerequisites are appropriately met, the Drug Controller will authorize it as a RMI through a letter of recognition; in the format given in Form 3G, within 60 days from the date of receipt of application.

If the RMI status is denied – the reasons are to be provided within 60 days from the date of receipt of application.

- **Order of Purchase of ENDs**

The order for purchase of each opioid and each formulation that is required, is then filled by the RMI and submitted to the licensed pharmaceutical agency along with a copy of RMI certificate.

If the annual estimate is utilized before time, the RMI can repeat the order of purchase of that amount, during the year as per the need, in case of unexpected increase in the number of patients needing ENDs.

The repeat order of purchase is best done with at least 3 months remaining for the existing stock of the drug to run out. This can prevent interruption in the availability of pain medication for the patients registered with the RMI.

- **Receipt of the consignment**

The applicant will get the original consignment of ENDs along with a copy in the format of Form No 3C Which contains the details of the consignment and the time of receipt.

Retain the original.

One copy is returned to the supplier and one copy is sent to the State Drug Controller.

- **Maintaining stock and records**

The consignment of ENDs is kept in a cupboard or locker safely under the supervision of the doctor in charge of the RMI.

Record of the consignment notes is maintained for two years

The quantity of each formulation of individual drug should be entered in a specified section of the END register which is prepared as per Form no 3H.

For e.g. if the RMI procures 10 mgs and 20 mgs tablets of oral Morphine, the stock of each should go into separate sections. Separate registers may also be maintained for each formulation.

Issues shall be under perpetual declining inventory and against prescription from the medical practitioner. The prescribing practitioner shall be responsible in case the prescription does not conform to statutory regulations. Nursing station shall ensure the entry of batch number in the prescription form while administering. Security clause for storage: All containers used for holding and storing narcotic drugs shall be properly labelled. Appropriate registers shall be maintained to have enough information on its usage.

- The name and address of each patient for whom END was prescribed is entered in the register along with the quantity disbursed. Record of every patient to whom END was dispensed is maintained in the format of Form 3E
- At the end of the day the total quantity of END disbursed that day, should be subtracted from the initial quantity with which the register was started. This amount naturally forms the initial quantity for the next day.
- Record of day to day accounts of every transactions in END is maintained in the format of Form 3D
- Once verified, the pharmacists in charge signs below the last entry of the day in the register.
- All records are kept for period of two years from the date of last entry.
- Although support staff may manage the day to day entries, the pharmacy in charge has primary responsibility of the stock and dispensing ENDs.
- The total quantity possessed by the RMI at any one time, should not exceed the submitted estimate (or revised estimate, if any). This quantity may be ordered repeatedly during the year, if the need for ENDs scales up during the year.
- If the requirement for ENDs has increased during the course of the year, the officer in charge of the RMI can submit the revised estimate for the same year by the 31st August. A brief justification for the same is provided while filing the annual return in Form--3 I.
- File annual return to the Controller of drugs, for the calendar year on or before 31st of March of the subsequent year in the format of Form 3 I.

Procedure for procurement, storage and dispensing of narcotic and psychotropic drugs

17.1 Purpose

- To provide guidelines governing adequate control for procurement, proper storage, dispensing and record keeping of Narcotic and Psychotropic Drugs in a Hospital.

17.2 Scope

- All the important activities related to the procurement, storage, dispensing and record keeping of Narcotic and Psychotropic Drugs in accordance with the Delhi Narcotic Drug Rules, 1985 as well as Drugs and Cosmetics Act, 1940 and Rules framed there under.

17.3 Responsibility

a. The Officer in-charge (Consultant/Doctor)

b. Pharmacist in-charge

c. Nursing Sister in-charge of respective departments of the hospital

d. Medical Administration

- Procedure

A separate license is required by the hospital for procurement, storage and distribution of Narcotic and Psychotropic Drugs from the local Excise Department.

- Storage

The Narcotic and Psychotropic Drugs must be stored under lock and key in a separate cupboard.

- Strict compliance of statutory requirements must be adhered to as provided under the Narcotic Drugs Rules, 1985, Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945 and Pharmacy Act, 1948.
- Narcotic drugs and psychotropic substances must only be dispensed by a pharmacist against a proper prescription of a doctor authorized for the purpose.
- Narcotic drugs and psychotropic substances must be procured and stored in such a manner so as to preclude their falling into the hands of unauthorized persons.

- The storage area for the narcotic drugs and psychotropic substances may be opened and accessed by specific Pharmacist in-charge and Nursing Sister in-charge of respective department.
- Cupboard or safe in which narcotic drugs and psychotropic substances are stored may be opened and accessed only when substances belonging to these categories are being placed into or taken out from the cupboard or room.
- Pharmacist in-charge must check physically at least once daily the stock of narcotic and psychotropic drugs stored. The same must be recorded in stock register and verified by the officer in-charge with signature and date.
- The prescribing practitioner shall be responsible in case the prescription does not conform to statutory regulations. Nursing station shall ensure the entry of batch number in the prescription form while administering.
- Appropriate registers shall be maintained to have information on usage. A proper record of their uses, administration and disposal shall be maintained at all the places wherever narcotic drugs are stored. The narcotic drugs register must incorporate a record of all receipt and issue involving narcotic drugs. The narcotic drugs register must be a bound register with consecutively numbered pages. A separate page must be used for each narcotic drug.
- Pharmacist shall be notified if any medicines or register is missing.

- Records

a. Separate stock register narcotic drugs in Pharmacy
b. Separate Issue Register for Every Formulary
c. Prescription should be as per the ACT and in Triplicate copy
d. Format for Ordering of ENDs Medicine as per Act

Procedure

- **Pharmacy**
  - Narcotics & Psychotropic substances are stored in Double Lock & Key in the Pharmacy.
  - The Key of the two lock should be with on duty two Pharmacists. The keys should be handed over to the person on duty after each shift.
  - NDPS Stock to be taken in every shift by Pharmacist on duty. Pharmacist on duty should verify the physical stock with the system stock.
  - The consultant prescribes the medication on the triplicate prescription pad (As per the NDPS Act) to the pharmacy and is dispensed from the Pharmacy. The following are to be verified
    - Date of the Narcotic Prescription
    - Name of the Patient
    - Address & Contact Details of the Patient
    - Name of the Drug
    - Quantity of the Drug
    - Name and Registration Number of the consultant prescribing the Narcotic Medicine
    - Signature of the consultant prescribing the Narcotic Medicine
  - A Prescription should contain only one drug name, for multiple narcotics different prescription to be used.
  - Narcotics should not be dispensed on old date prescription or if the prescription is not legible or changes are made to the original prescription.

- If changes are made to the original prescription it should be signed by the consultant at appropriate place where change has been done.
- After confirming all details on the prescription, narcotics are dispensed by the Pharmacist to the Patient (For Out Patient) and to the Staff Nurse/ Doctor/ RMO (for In Patient).
- When the dosage form of the Narcotic is tablet/ capsule, the number of units dispensed should be equal to the number of units prescribed.
- A bill is generated for the same & entries of dispensing to be done in “Narcotics Drug Issue Register”.
- A separate register to be maintained in the Pharmacy for different Narcotics stored.
- One copy of the prescription stamped with “Dispensed Medicine” with signature of dispensing Pharmacist to be given to Patient (To be kept in Patient File for In Patient) along with the bill.
- Empty Ampoule Register to be maintained in the Pharmacy. The Empty ampoule received from the unit should match to the dispensed quantity in that unit. Empty Ampoule should be returned with patient sticker attached to it.
- Method of Discard of Empty Ampoules :

Crushing of the empty ampoule should be done by Pharmacist in presence of Pharmacy In charge & record to be maintained for the same

or

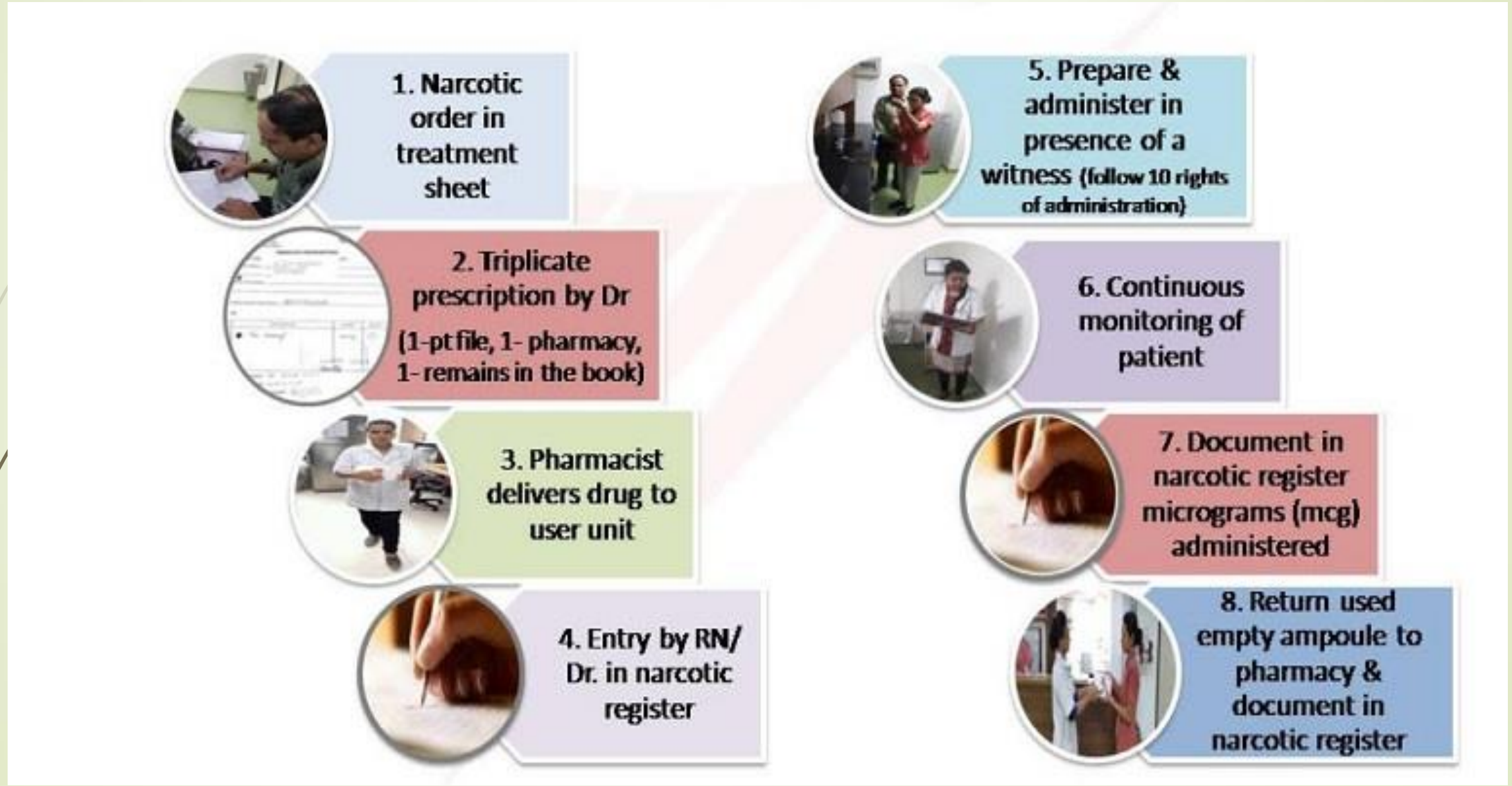
The Empty Ampoule is immersed in 1% Hypochlorite solution in presence of the Competent Authority and the entry for the same is made in the register and signed by the appropriate authority and should be available for inspection as deemed needed

- For returning of the unused Narcotic vials/ ampoules, prescription in triplicate to be received in the Pharmacy with **“Return”** mentioned on the top of the three prescriptions, and the details to be verified before returning the medicine. After returning the medicine entries to be made in the Narcotics register.

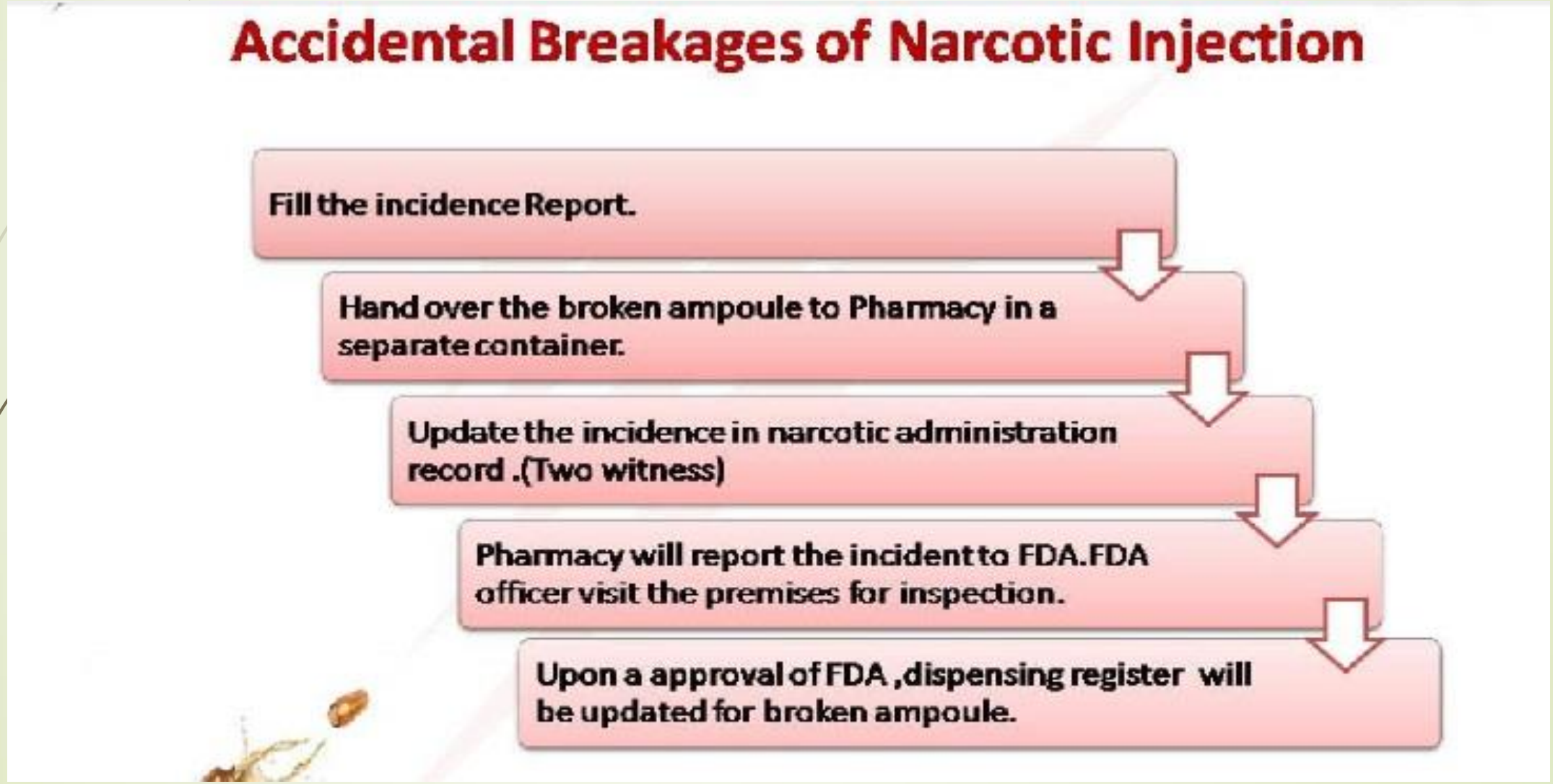
Patient Care Area :(OT, Cath Lab, Emergency, ICU, Wards)

- The staff Nurse should indent the Narcotics, through the system based on the requirement of the patient.
- Prescription in triplicate to be send to Pharmacy by the Staff Nurse to the Pharmacy for the procurement.
- Three Prescriptions should be clear & as per provision of FDA guidelines.
- The Pharmacist will dispense the indent only when the triplicate prescriptions are received by the pharmacist in the Pharmacy.
- Once the triplicate prescription is received in the Pharmacy, the medicines are dispensed through the system and two printouts of the indents are generated.
- The Pharmacist hands over the narcotic medicine to concerned staff nurse, and signature of the staff nurse is taken on the Narcotic register.
- The Narcotic Drug shall be prepared and administered by the assigned Nurse in the presence of the Nurse Manager/Team Leader only, who both has to document the same.
- The Patient care area to maintain their “Narcotic Usage Register”. The staff Nurse will make an entry into the Narcotics Usage Register after administration of the drug. This register is to be periodically checked by Nursing In charge.
- Unused or the left over drug shall be kept in Narcotics Cupboard.
- Narcotic Cupboard should have Double Lock & Key; one key should be with Team Leader/ Nurse Manager & another with Senior Nurse in the department.
- Narcotic Injection to be disposed if it is not used after 24 hour of preparation, it should be disposed immediately in to the sink with tap open to flush out the drug in the presence of witness and the same shall be documented in the “Narcotic Usage Register”
- Patches to be folded with the sticky ends together and discarded in dustbin.
- Incase of accidental breakage of any ampoule, an Incident form shall be filled handed over to the Nursing Officer as per the defined protocol.
- Empty Ampoule should be returned with patient sticker attached to it. Documentation for returning the empty ampoule should be done in Narcotic Usage Register, mentioning the pharmacist name to whom it was returned.
- Any excess ampoules not utilized for patients (after discontinuation of use or death of patient) the unused vials are sent back to the pharmacy with proper documentation immediately.

Flow Chart for Use of Narcotic in Hospital



Flow Chart for Narcotic Injections



Unused/Leftover Drug Discarding

Narcotic Register

Narcotic Usage Register						Narcotic Usage Register							
Date & Time	IP No.	Name of Patient	Ordered by Doctor	Name of the Drug ordered	Quantity Received from Pharmacy	Administered to Patient			Unused Narcotics Discarded			Empty Ampoules	
						Quantity	Administered By	Witness By	Quantity	Discarded by	Witness By	Handed Over By	Received by Pharmacist

Thank You