



SAFETY



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SECTIONS





PHARMACY MANAGEMENT

- Procurement, storage, dispensing of:
 Regular, High-risk, Emergency & Narcotic drugs, Short expiry, Implantable prosthesis
- MEDICATION ADMINISTRATION
 Safe prescription, preparation, administration of
 - o Regular drugs, self administered drugs, infusions and radioactive drugs
- CHEMOTHERAPY
- ADVERSE DRUG EVENTS
 - Medication errors, ADR.
- MEDICATION MANAGEMENT
 - Pharmaco-therapeutic committee, statutory licences, documents, policies and SOPs





PHARMACY MANAGEMENT

- *PROCUREMENT
- ***INVENTORY MANAGEMENT**
- * STORAGE
- *DISPENSING OF: REGULAR HIGH-RISK, EMERGENCY & NARCOTIC DRUGS





SAFE PROCUREMENT





Vendors can be selected based on the following certificates

- GMP certificate
- FDA approval (for implantable prosthesis)
- Whole sale drug license (Form 20B and 21B)
- Approval from DCGI (Drugs control general of India)/ State Drugs controller
- Vendor selection checklist



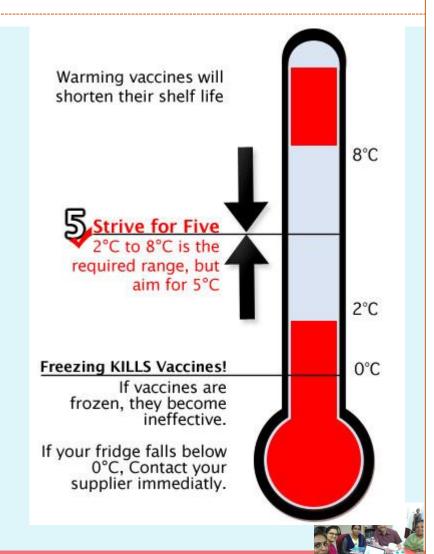


SAFE STORAGE



- Stored as per manufacture's recommendation
- Room temperature 16°C to 24°C
- Refrigerator Temperature 2°C to 8°C (12 hourly monitoring documentation)





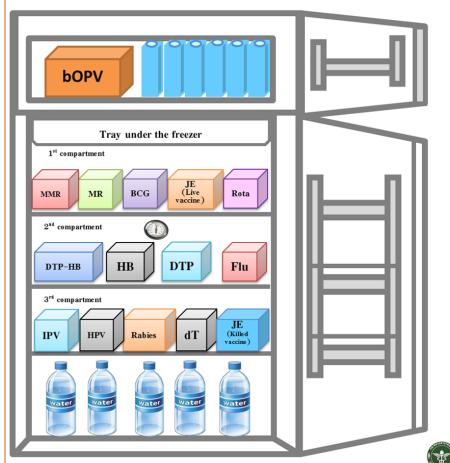


VACCINE STORAGE





GUIDANCE FOR STORAGE OF REFRIGERATED VACCINES



Vaccine	Temperature
bOPV	-15°C to - 25°C
BCG	
JE (Live vaccine)	+2°C to +8°C (Live vaccines should be
MR	stored in refrigerator compartment. Do NOT
MMR	store them in tray under the freezer)
Rota	
НВ	
DTP	
ртр-нв,	+2°C to +8°C
JE (Killed vaccine)	(Store freeze sensitive vaccines in the
dT	refrigerator compartment between +2°C to +8°C.
HPV	Do NOT store them in the freezer or in the first
IPV	compartment)
Flu	
Rabies	

Vaccines
should be
stored
according to
National/
International
guidelines

Notes: 1. Store diluent between +2°C to +8°C, no diluent in the freezer.

2. No vaccine in the refrigerator doors..

Expanded Program on Immunization (EPI Section), Bureau of General Communicable Diseases, Ministry of Public Health, Thailand







• Theft Free

- o CCTV
- Restricted entry
- Narcotics- restricted access



- Alphabetical order
- FIFO











- The High risk Medicines, Look Alike and Sound Alike can be color coded as per organizations policy
- The Look Alike and Sound Alike medicines are to be stored physically separate.
- High Risk medicines are stored separately.
- The list of LASA and High risk medicines are to be defined and displayed in the pharmacy.





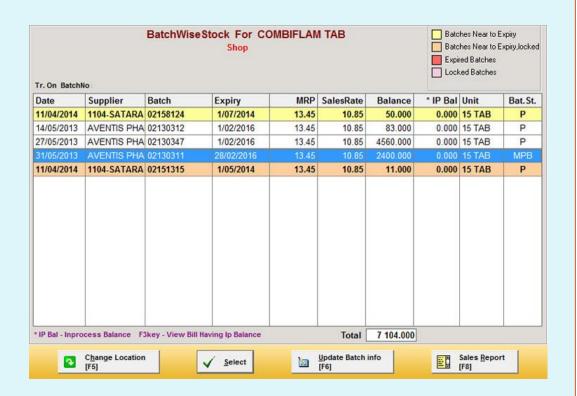






Near expiry (notification alarms)

- According to the organization's policy (usually 3 months before the expiry) not stored in the hospital
- o The Near expiry medicines are collected from all levels of storages from the hospital.
- The near expiry medicines can be returned to Vendor (if a hospital does have a MOU stating the returns)
- The Expired medicines are to be discarded as per National Standards and guidelines.









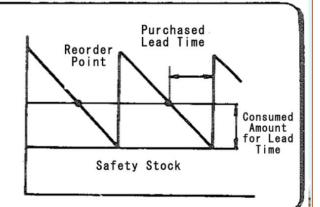
RE- ORDER LEVEL:

- Reorder level (or reorder point) is the inventory level at which a company would place a new order or start a new manufacturing run.
- FORMULA:

Reorder Level = Lead Time in Days \times Daily Average Usage

- Lead time is the time it takes the supplier or the manufacturing process to provide the ordered units.
- o Daily average usage is the number of units used each day.

Reorder Point = Consumed Amount per day x Purchased Lead Time + Safety Stock Quantity







SAFE DISPENSING



- Right medication
 as per prescription
 and expiry check –
 Before dispensing
- Cut strips Batch Number, Expiry date

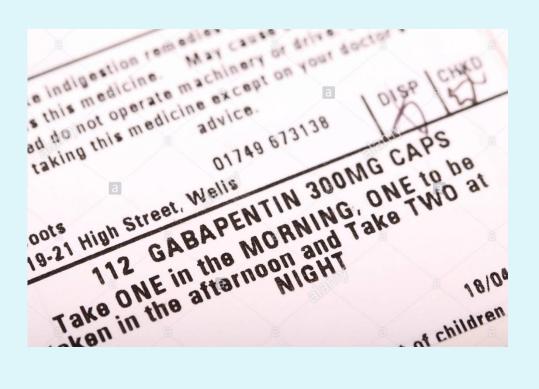








• Dosage, Time, Before/ after food to be written and verbally explained during dispensing.









HIGH RISK & EMERGENCY MEDICATIONS



- Double level check prior to the dispensing and administration (same nurse/ pharmacist or two nurses/ pharmacist)
- The double level checking should be done for narcotics, High risk medicines and LASA medicines.







MEDICATION ADMINISTRATION



- * SAFE PRESCRIPTION
- * PREPARATION
- * ADMINISTRATION OF REGULAR DRUGS
- * SELF ADMINISTERED DRUGS
- * INFUSIONS
- * RADIOACTIVE DRUGS.
- ***CHEMOTHERAPY**





SAFE PRESCRIPTION

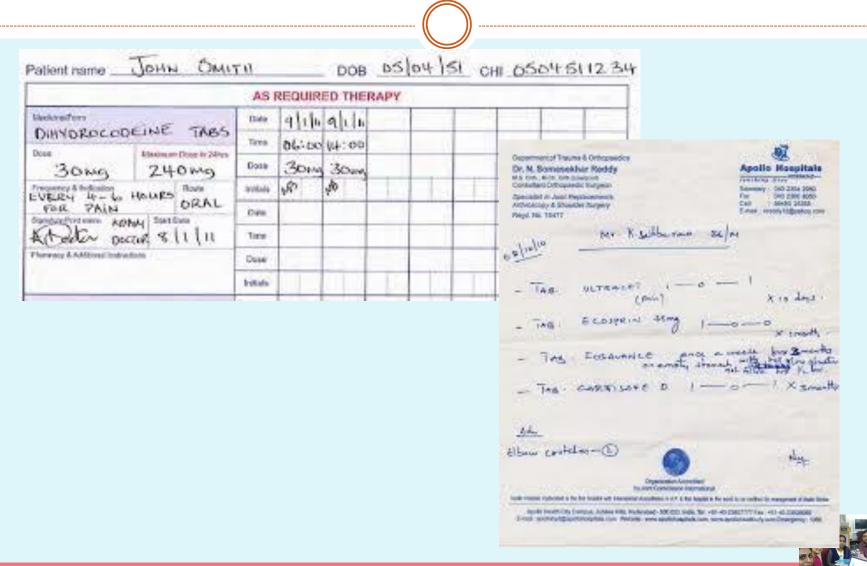


- Standard OP prescription format
- Uniform locations in IP case sheet
- Block Letters
- Legible hand writing strength, frequency, dose and route
- Dated, Timed and signed with Name
- Approved abbreviations and symbols to be used
- No acronyms
- Generic names
- Prescription Audit











SAFE DRUG PREPARATION





- The prepared drugs should contain labeled with the following
 - o Drug name
 - Dilution
 - Dose/ infusion rate
 - Route
 - Preparation time
 - o expiry
- The second drug should not be prepared before labeling the first drug
- Any unlabeled infusions/ fluids are to be discarded.

SYRINGE N	MEDICATION	
PATIENT		
DRUG		
AMT		_ /ml
PREPARED DATE	TIME	
PREPARED BY		
EXPIRES DATE	TIME	





SAFE ADMINISTRATION



RIGHTS

- Patient
- Medication
- Dose
- Route
- Time (30 mins before/ after the specified time)
- Documentation
- Expiry is checked
- Self Administration Policy







SELF MEDICATION & ADMINISTRATION



- Hospital should have self medication policy
- Documentation of self administration should be done
 - o Name of the drug
 - Dosage
 - Route
 - o Time
 - Mentioning self administered by patient





SAFE INFUSIONS



- The safe infusions practice should capture the following
 - Start time
 - Rate of infusion
 - End time
 - Name and strength of medicine.

DRUG INFUSION VIA SYRINGE DISCONTINUE IF CLOUDINESS OR PRECIPITATE OCCURS					
PATIENTS NAM	ИE		REG. NO.	WARD	
ROUTE DRUG APPROVED NAME(S)		Total amount added		Infusion rate per hour (Please state millilitres or millimetres)	
Diluent:		Total Volume to:	Type of pump:		
Prepared Changed by:	Checked by:	Date:	Duration	Time started	

DRUG ADDED	TO
INFUSION FLU	ID

DRUG ADDED BY

QUANTITY CHECKED BY

DATE TIME

RETURN TO PHARMACY IF UNUSED 12 HOURS
AFTER ADDITION OF DRUGS



NARCOTIC DRUGS





- The narcotics medicines are stored with limited access (double lock, finger print lock etc)
- The narcotics register should contain the following
 - Name of the patient
 - o UHID number
 - Narcotics prescribed
 - Prescribed by
 - Administered by
 - Quantity administered.
 - Quantity discarded
 - Discarded by
 - Witnessed by
 - No of empty vials returned.
- The remaining narcotics medicines are discarded in running tap water with witness.



RADIOACTIVE DRUGS





Administered by trained staffs

Written documentation of radioactive medication

- o Receipt
- Identification
- Labeling
- Storage
- Control
- Distribution
- o disposal
- Discarding as per AERB guidelines
- Proper signage
- Details of delay tanks
- Environmental Radiation exposure test



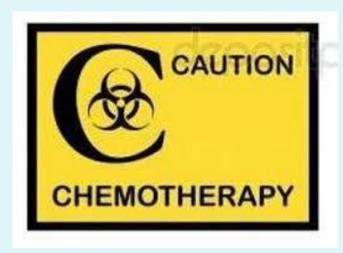






Storage

- It is regulated that there be adequate ventilation in the area, negative pressure and preferably vented to the outside.
- Establish a dedicated negative-pressure storage area for cytotoxic drugs that minimizes the risk of contamination.











PREPARATION OF CHEMOTHERAPY DRUGS

- The preparation and administration of drugs are done by trained staff
- all mixing, and preparation of administration sets with a cytotoxic drug be performed in one centralized area in a specially designated *class II type B biological safety cabinet that*:
 - is exhausted through a HEPA filter to the outside atmosphere in a manner that prevents recirculation into any inside area
 - has exhaust and ventilation systems that remain in operation for a sufficient period of time to ensure that no contaminants escape from the biological safety cabinet into the workplace
 - is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.









PPE WHILE PREPARATION OF DRUGS

• Workers wear PPE, a cap, surgical/procedure mask, shoe covers, a protective gown and two (2) pairs of gloves to make sterile preparations of cytotoxic drugs in preparation cabinets.











- All the prepared medicines are to be labeled with drug name, prepared dare, time and expired date.
- The personal protective equipments are to be worn during administration also.
- Cytotoxic drug spillage kits are to be available in receiving, storage, preparation and also in administration area.







DISPOSAL OF CYTOTOXIC DRUGS

	Consists of	Disposal	
Human Anatomical Waste	Human tissues, organs, body parts	Incineration/deep burist	
Animal Waste	Animal tissues, animals used in research, waste from veterinary hospitals, colleges, and animal houses	Incineration/deep burial	
Microbiology & Biotechnology Waste	Wastes from laboratory cultures, stocks or specimens of micro organisms, live or attenuated vaccines, toxins, dishes and devices used for transfer of cultures	Incineration	
Waste sharps	Needles, syringes, scalpels, blades, plass etc.	Auto claving/shredding	
Discarded Medicines and Cytotoxic drugs	Outdated, contaminated and discarded medicines	Incineration and secured landfills	







ADVERSE DRUG EVENTS

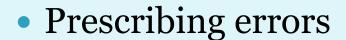
MEDICATION ERRORS, ADR



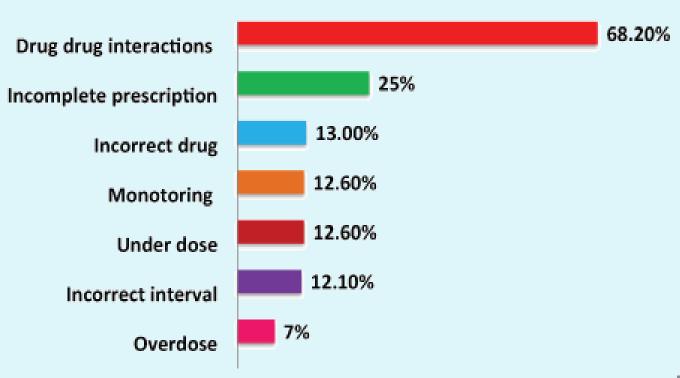








Prescribers Errors











Table

Prescriber's Intention	Misinterpretation
AD, AS, AU (right ear, left ear, each ear)	OD, OS, OU (right eye, left eye, each eye)
qod (every other day)	qd (daily) or qid (4 times a day)
U or u (units)	Zero, causing a 10-fold increase in dose (eg, 4U to 40)
Trailing zero (1.0 mg)	1.0 mg mistaken as 10 mg
Naked decimal point (.5 mg)	.5 mg mistaken as 5 mg
Drug name and dose run together (Inderal40)	Mistaken as Inderal 140
Large doses without properly placed commas	100000 units mistaken as 10,000 units
AZT (zidovudine)	Mistaken as azathioprine or aztreonam

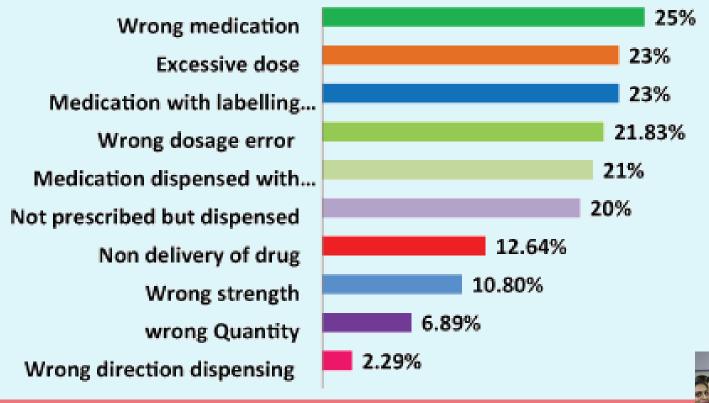






Dispensing errors

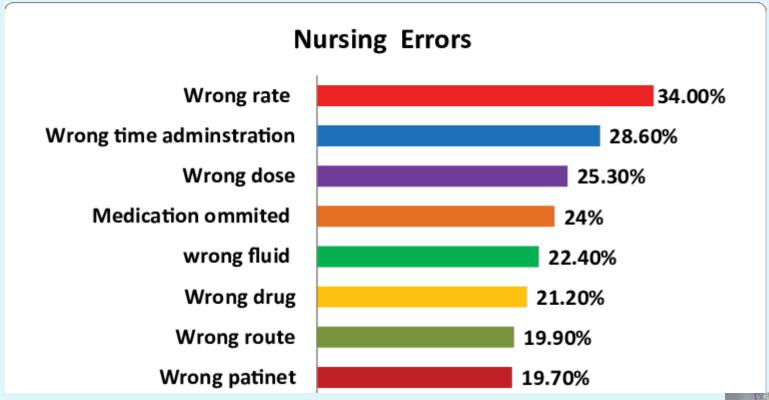
Pharmacist Errors







Administration errors









- These errors are documented and reported in Medication error reporting form.
- The Medication error reporting form consists of
 - Drugs involved
 - Outcome of the error (harm/no harm)
 - Potential causes of error (illegible prescription, lack of knowledge, LASA)
 - Intervention done (administered antidote, changed to correct drug/dose, provided education)

(the errors percentage pictures in previous slides are taken from medication errors)







1. Date of eve	Jewsharial Institute appropriate box, All field	Medical (A	tion E blame led exc on of s	rror Reporting For free reporting tool) cept details of reporter w	which is optional.
3. Type of er Presorit Admini 5. Descriptio	ing Disponsing	ecity)		Petions details: Age: Disgrosis: and how was it detect	Gender:
9. Possible or Lack of in experienc linguish p Lock after reductio	e informescription PANA if sound after Mac Fally seling / instruction proces	Sinengih Pres		7. Did the error reach Yes 8. Outcome of the evi No error A. Events have potential to cause error Serror, No haves B. Error did not reach patient G. No harm but requires monitoring 10. Details of report harne: Designation: Matthe Na:	Mo Rent: Error, here E. Temporary harm requiring treatment P. Temporary harm requiring heatment P. Temporary harm requiring Page 18 permanent harm H. Near death 1. Death
☐ Education	en done: red antidate / training provided part who made error	Communi	cation p	of drug I dose / frequency racess improved o changed / instituted	Pie-action needed Others (specify)

http://jipmer.edu.in/sites/default/files/Medication-error-reporting-form.pdf





ADVERSE DRUG REACTION





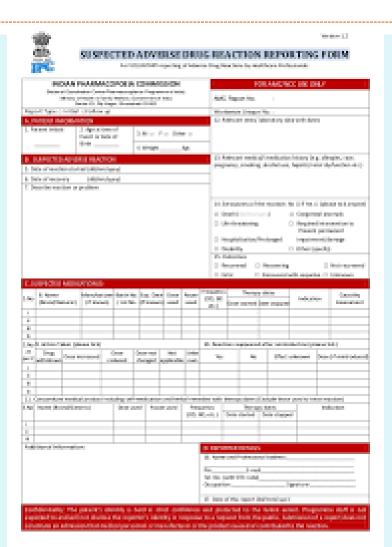
- All the medications are monitored after administration
- Any reaction developed, Stop the medication
- Report to Treating doctor, clinical pharmacist
- Adverse drug reaction form is documented.
 - Date of reaction
 - Date of recovery
 - o Problem/ reaction
 - Drugs involved
 - Reaction abated after drug stopped
 - Reactions reappeared after reintroduction
 - Relevant tests/ laboratory data with dates
 - Other relevant history
 - Seriousness of reaction
 - Outcomes





ADR REPORTING





http://www.cdsco.nic.in/writereaddata/A DR%20form%20PvPI.pdf







MEDICATION MANAGEMENT



PHARMACO-THERAPEUTIC COMMITTEE, STATUTORY LICENCES, DOCUMENTS, POLICIES AND SOPS







PHARMACO THERAPEUTIC COMMITTEE



- Approves formulary
- Defines LASA
- Defines High Risk medicines
- Medication error report Audits- CAPA
- ADR- CAPA
- Dilution errors Review and CAPA
- Approval of new drug requisition from consultants
- Approval of Implantable prosthesis.

- Regulates the procurement process
- Approves vendors based on the checklist and criteria.
- Drug interactions review
- Duplications review
- Indicators review
- Radiation safety
- Facility rounds and internal audits





IMPLANT MANAGEMENT





- The selection of implants should be based on national and international guidelines. Certified with GMP, FDA, etc.,
- Selection of implants are done by consultants in pharmaco therapeutic committee
- The Implants are to be purchased by pharmacy purchase requests.
- Patients and family to be educated about precautions to be taken





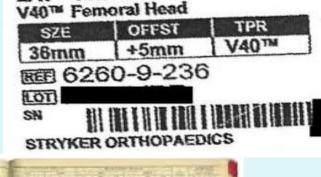




• The Implant sticker such as manufacturer, type, size, batch number and serial number/ any other important details should be documented in the following areas.

- Theatre log book/ implant register.
- Surgery notes
- Discharge summary
- If the stickers are not

available, the details can be printed documented in the areas to be documented.









STATUTORY LICENSING



- Pharmacy licenses
- Narcotics License
- Pharmacist license
- AERB registration and approvals
- RSO certification
- FSSI





DOCUMENTATION



- List of approved vendors
- Purchase orders
- Implant policy
- Implant register
- Temperature monitoring
- Fridge list
- LASA list
- Near expiry list

- Emergency drug list
- High risk medication list
- Crash cart checklist
- OP prescription
- IP drug chart
- Narcotic drug register
- ADR reporting form
- Incident reporting form
- Training records





POLICIES & SOP





- Purchase, storage, environment, prescription and dispensing
- Implants
- Identification & storage of LASA
- Expired drugs
- Emergency drugs
- Prescriptions, medication orders, verbal orders for regular drugs, high risk drugs and emergency drugs
- expired drugs
- Narcotic drugs
- ADE
- Radioactive drugs
- Medication administration SOP









