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"WORKING TOWARDS BEING THE BEST"

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Unit: IV

Topic: *Pharmaceutical Waste Treatment and Disposal Practices*

Pharmaceutical Waste Treatment and Disposal Practices

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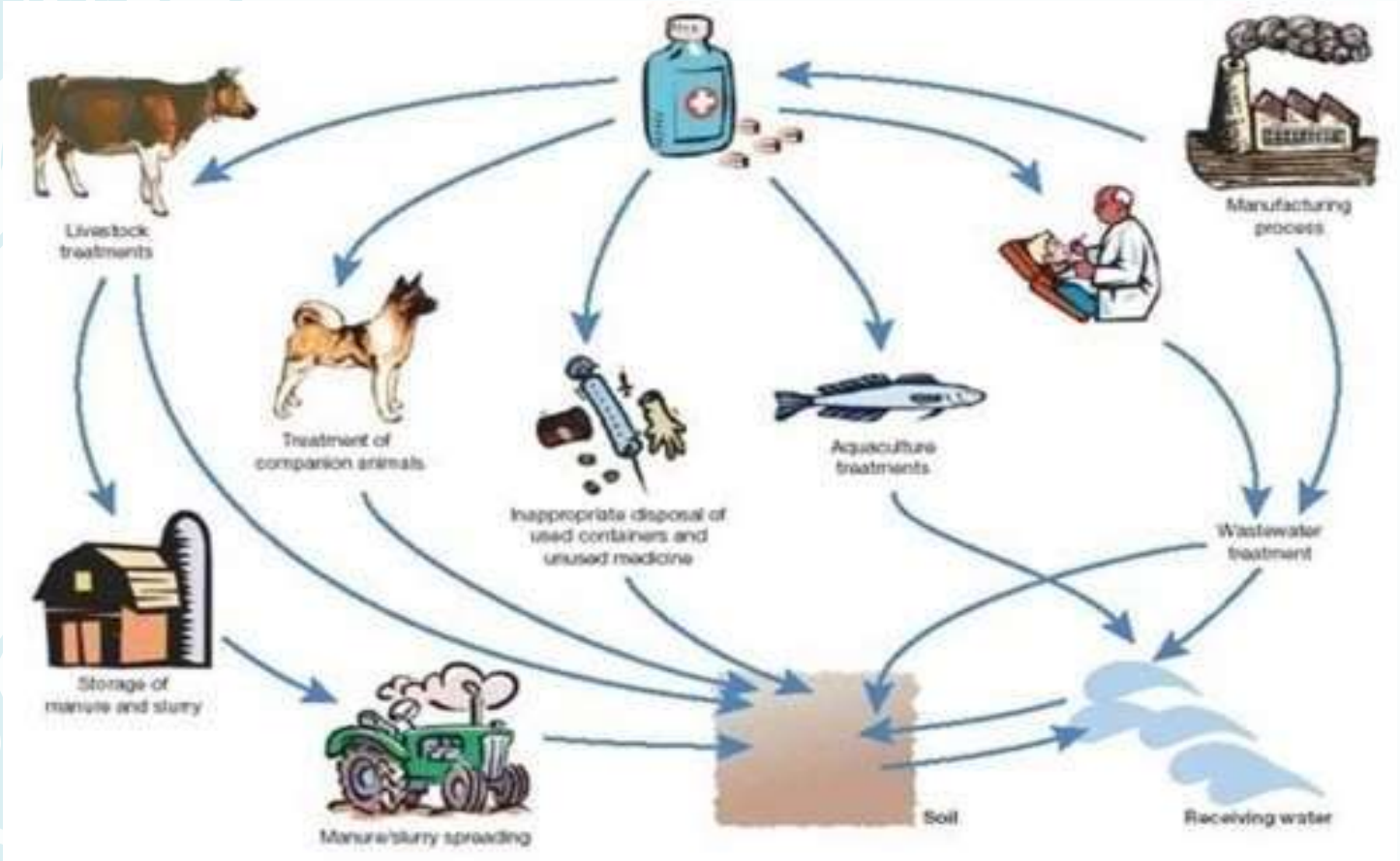
1.Introduction

- Treatment of pharmaceutical waste is very important because improper disposal may also have an adverse effect on land values, create public nuisances, otherwise; the failure or inability to salvage and reuse such materials economically results in the unnecessary waste and depletion of natural resources (**Eliassen, 1969**).

Cont…

Improper disposal of medication has several possible consequences such as childhood poisoning, environmental pollution, a negative impact on wildlife, and antibiotic resistance.



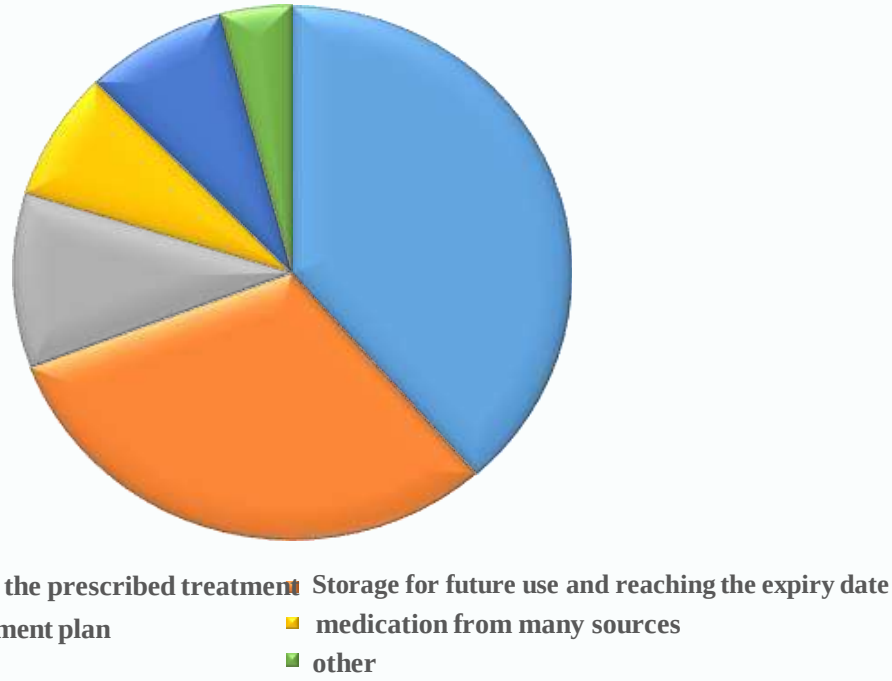
2.Existence of unused medicines.

The main reason that respondents gave for having unused medicines at home were:

1. lack of adherence to the prescribed treatment.
2. Storage for future use and reaching the expiry date.
3. Changing the treatment plan while the patient still has stock from the old medication or the discontinues order not activated by the pharmacy.
4. Same patient follow up in many hospitals.
5. Patient death.

Existence of unused medicines: data according to the medication collected in Riyadh 20th December 2017 to 20th March 2018 (218families)

Existence of unused medicines	number of families	%
lack of adherence to the prescribed treatment	84	38.5
Storage for future use and reaching the expiry date	67	30.7
Changing the treatment plan	23	10.5
medication from many sources	17	7.8
patient death	18	8.2
other	9	4.1
Total	218	100



PHARMACEUTICAL WASTE COMPOSITION

- Organic chemical residues from manufacturing processes
- Helogenated/non-helogenated sludges and solids
- Sludge & tars
- Heavy metals
- Test animal remains

Contd...

- Return pharmaceuticals

- Low-level radioactive waste

- Biological products including materials extracted from biological materials such as vaccines, serums, and various plasma derivatives.

- Contaminated gloves, filters, clothings, etc

IMPORTANCE OF TREATMENT

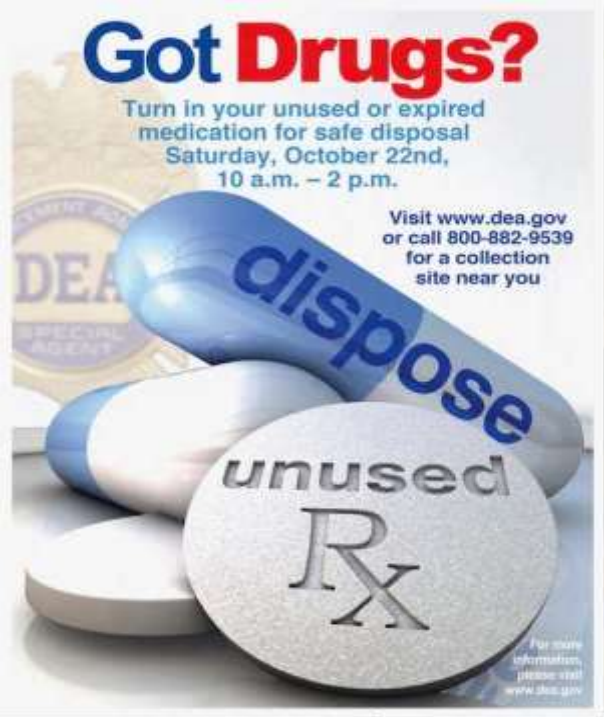
Treatment of solid pharmaceutical waste has great importance because of (Wagner 1991)

- **Safety related properties**
  - corrosive (solvents and acids used in the preparation of some medicine)
  - flammable (most of the medicines containing alcohol, sprit, tincture etc.)
  - reactive (organic acids used as a component in the preparation of some pain killers and syrups)
  - ignitable (most of the solvents used in the preparation of medicines)

- **Health related properties**

  - irritant (allergic response e.g. penicillin, ferric compounds)
  - toxic when ingestion (medicines for external use e.g. tincture, potassium iodide etc.)
  - radioactive (medicines used for chemotherapy and cancer treatment)
  - carcinogenic (persistent use of some medicines)

Medicine take-back programs are the only secure and environmentally sound way



US Drug Enforcement Administration (DEA)

ADMINISTRATION

FDA U.S. FOOD & DRUG

Where and How to Dispose of Unused Medicines Updated

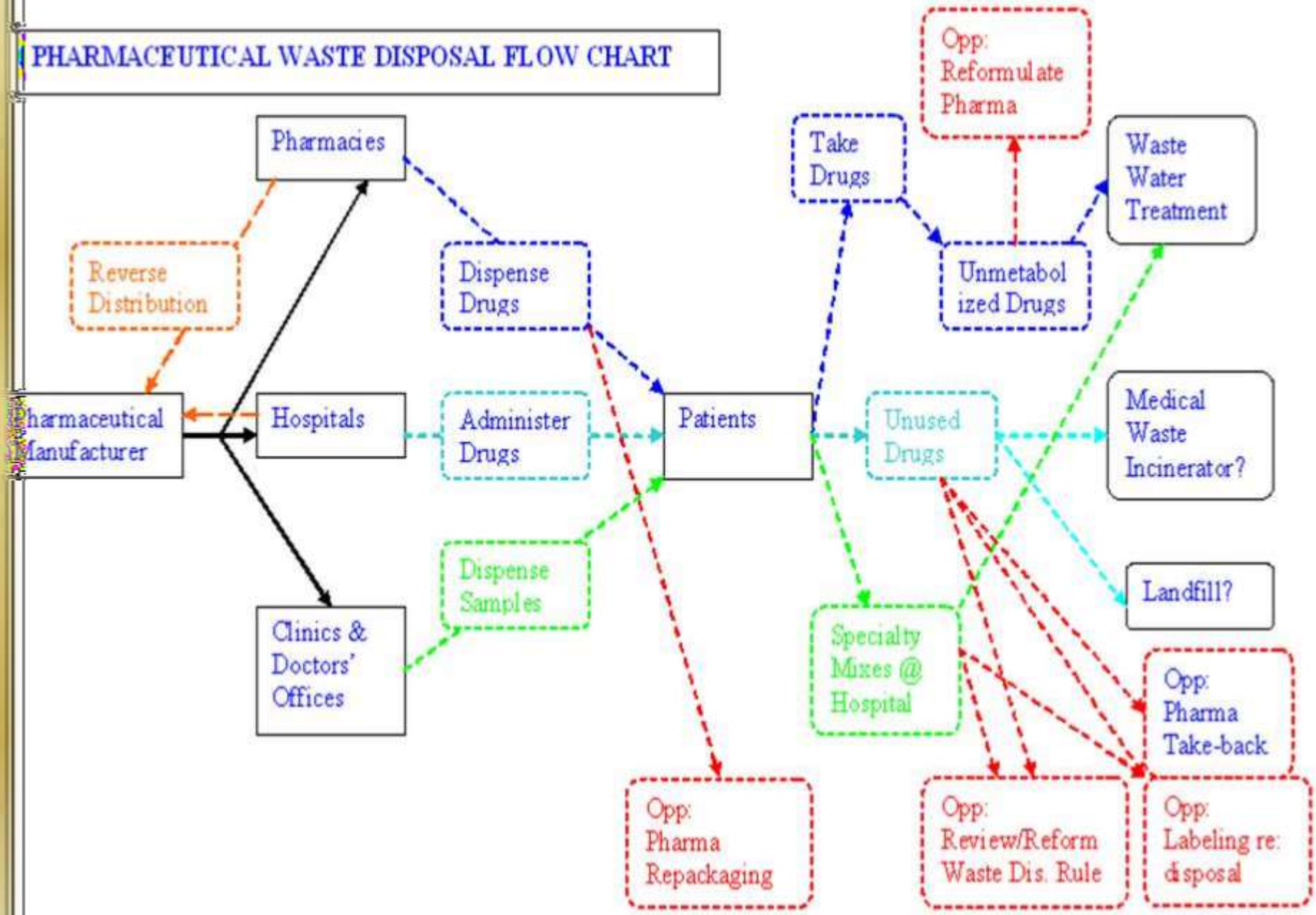
https://www.fda.gov/default.htm

3.Flushing of Certain Medicines

A small number of medicines may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. To prevent accidental exposure to, including ingestion of, these potentially dangerous medicines by children and others, including pets, it is recommended that these medicines be disposed of quickly through a medicine take-back program or by transferring them to a DEA-authorized collector. If these disposal options are not readily available, it is recommended that these medicines be flushed down the toilet as soon as they are no longer needed.

OBJECTIVE OF PHARMACEUTICAL WASTE TREATMENT

- The objectives of pharmaceutical waste treatment are the destruction or recovery for reuse and/or the conversion of these substances to innocuous forms that are acceptable for uncontrolled disposal.


PHARMACEUTICAL WASTE DISPOSAL FLOW CHART
Pharmacies
Reverse Distribution
Dispense Drugs
Take Drugs
Opp: Reformulate Pharma
Waste Water Treatment
Unmetabol ized Drugs
harmaceutical Manufacturer
Hospitals
Administer Drugs
Patients
Unused Drugs
Medical Waste Incinerator?
Landfill?
Dispense Samples
Specialty Mixes @ Hospital
Clinics & Doctors' Offices
Opp: Pharma Take-back
Opp: Pharma Repackaging
Opp: Review/Reform Waste Dis. Rule
Opp: Labeling re: disposal

4.Disposal methods

- **2.1 Return to donor or manufacturer**

  ➢ Returning unusable drugs for safe disposal by the manufacturer, such as anti-neoplastics.

  ➢For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date, it may be possible to return them to the donor for disposal.

- **Cross–frontier transfer of pharmaceutical waste**

  ➢There are currently no international conventions regulating transfer of pharmaceutical products across frontiers.

  ➢ Obtain permission to cross international borders along the transit route prior to actual transport.

  ➢ These procedures can take several months to complete.

2.2 Landfill

- Place waste directly into a land disposal site without prior treatment or preparation.
- Oldest and the most widely practiced method of disposing of solid waste.
- Three types are recognized.
- **Open uncontrolled non-engineered dump**
- **Engineered landfill**
- **Highly engineered sanitary landfill**

Open uncontrolled non-engineered dump

- The most common land disposal method in developing countries.
- Untreated waste discharged into an uncontrolled, non-engineered open dump does not protect the local environment and should not be used.
- They should preferably be discharged after immobilization by encapsulation or inertization.
- Can lead to pollution,with the risk of drinking water contamination in the worst cases.

- **Engineered landfill**
- Such a landfill has some features to protect from loss of chemicals into the aquifer.
- Direct deposit of pharmaceuticals is second best to discharging immobilized pharmaceutical waste into such a landfill.

- **Highly engineered sanitary landfill**
- Properly constructed and operated landfill sites offer a relatively safe disposal route for municipal solid wastes, including waste pharmaceuticals.
- The top priority is protection of the aquifer. An appropriate landfill consists of an evacuated pit isolated from watercourses and above the water table.
- Each day's solid waste is compacted and covered with soil to maintain sanitary conditions.
- The term "safe sanitary landfill" refers to such a site that is adequately situated, constructed and managed

2.3 Waste immobilization: Encapsulation

- Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum.
- Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously.
- They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand.
- For ease and speed of filling, the drum lids should be cut open and bent back.
- Care should be taken to avoid cuts to hands when placing pharmaceuticals in the drums.

Encapsulation

Contd.

- Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity.
- A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency.
- Steel drum lids should then be bent back and sealed, ideally by seam or spot welding.
- The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste.

2.4 Waste immobilization: inertization

- Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals.
- Pills need to be removed from their blister packs.
- The pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste.
- The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste.

Contd...

- The paste then sets as a solid mass dispersed within the municipal solid waste.
- The process is relatively inexpensive and can be carried out with unsophisticated equipment.
- The approximate ratios by weight used are as follows:
  - Pharmaceutical waste: 65%
  - Lime: 15%
  - Cement: 15%
  - Water: 5% or more to form a proper liquid consistency

2.5 Sewer

- Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water
- Then, flushed into the sewers in small quantities over a period of time without serious public health or environmental affect.
- Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics.

2.6 Burning in open containers

- Pharmaceuticals should not be destroyed by burning at low temperature in open containers, as toxic pollutants may be released into the air.
- Polyvinyl chloride (PVC) plastic however must not be burnt.
- While burning pharmaceutical waste is not advocated as a method of disposal, it is recognized that it is not infrequently used.
- It is strongly recommended that only very small quantities of waste pharmaceuticals be disposed of in this way.

2.7 Medium temperature incineration

- In many countries there are no high temperature, two–chamber incinerators designed to handle more than 1% halogenated compounds.
- In emergency situations the responsible authorities may consider it acceptable to treat expired solid form pharmaceuticals using a two–chamber incinerator that operates at the minimum temperature of 850°C, with a combustion retention time of at least two seconds in the second chamber.
- In this case, it is recommended that the pharmaceutical waste is diluted with large quantities of municipal waste (approximately 1:1000)

2.8 High temperature incineration using existing industrial plants

- Cement kilns(that operate at temperatures well in excess of 850°C) are particularly suited for the disposal of expired pharmaceuticals, chemical waste, used oil, tyres, etc.

- During burning the cement raw materials reach temperatures of 1450°C, while the combustion gases reach temperatures up to 2000°C.

- The gas residence time at these high temperatures is several seconds.

- In these conditions all organic waste components are effectively disintegrated.

- Some potentially dangerous or toxic combustion products become adsorbed into the cement clinker product or are removed in the heat exchange equipment.

Contd...

- Cement producers in many countries are keen to use alternative fuels, as their use reduces the fuel bill without adversely affecting the quality of the cement.
- Pharmaceuticals should be introduced into the furnace as a reasonably small proportion of the total fuel feed.
- It is suggested that as a sensible "rule of thumb" no more than 5% of the fuel fed into the furnace at any one time is pharmaceutical material.
- Cement kilns typically produce 1,500 to 8,000 metric tons of cement per day and therefore quite large quantities of pharmaceutical material can be disposed of in a short period.

2.9 Chemical decomposition

- If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill.
- Chemical inactivation is tedious and time consuming, and stocks of the chemicals used in treatment must be made available at all times.
- For disposal of a small quantity of anti-neoplastic drugs this method may be practical.

3. Sorting categories

- **3.1 The objectives of sorting:**

- To separate the pharmaceuticals into categories that require different disposal methods.
- The appropriate safe disposal method recommended will depend principally on the pharmaceutical dosage form of the drugs.
- An initial overall evaluation of the stockpile and subsequent division of pharmaceuticals into those suitable for use and those to be discarded.

The sorting process includes:

- ✓ Identifying each item
- ✓ Making a decision on whether it is usable
- ✓ If usable, leaving packaging intact
- ✓ If not usable, making a judgement on the optimal method of disposal and sorting accordingly
- ✓ Leaving packages and boxes intact until reaching their location, prior to definitive disposal or transport to an institution for use.

3.2 Optimum conditions for sorting

- Sorting should be done in the open or in a well ventilated place
- Sorting should be done as close as possible to the stockpile in an orderly way, with all sorted material clearly labelled and separated at all times.
- Staff supplied with protective equipment (gloves, boots, overalls, dust masks, etc.)
- Once sorted, the pharmaceuticals should be carefully packed with the contents clearly indicated on the outside of the containers.
- The materials should be kept in a dry secure and preferably separate.

3.3 Sorting categories

- The top priority of the sorting process is to separate out the pharmaceuticals that are categorized as controlled substances (e.g. narcotics), antineoplastic (cytotoxic-anti cancer) drugs any other hazardous non-pharmaceutical products that may have been mixed among the pharmaceuticals.
- The remaining unwanted pharmaceuticals must be further sorted into different categories by dosage form, (capsules, powders, solutions, suppositories, syrups, tablets)

3.4 Pharmaceuticals & other materials which can still be used

- The first step in dealing with these stockpiles is to remove and dispose of these non-drug, non-chemical items.

- ***Non-pharmaceutical useful materials***

- Medical equipment, beds, wheelchairs, dressings, clothing, laboratory glassware, etc. can either be utilized by the institution or by other facilities, recycled, cannibalized for spare parts or disposed to a landfill.

Useful pharmaceuticals

- If feasible, pharmaceuticals within their expiry date and considered useful should be separated out and immediately used by the institution or reallocated according to the needs and instructions of the regional health authorities.
- A list can be prepared giving details of the items available, quantities and expiry dates and circulated to others who can use the materials.

Chemicals

- Acids, alkalis, reagents, phenol-based chemicals used for cleaning floors, disinfectants, etc. can be put to good use.
- If large quantities of these items are found a list may be prepared and offered to other potential users, such as hospitals, universities, or school laboratories, etc

3.5 Expired or unwanted pharmaceuticals

Pharmaceuticals that should never be used and should always be considered as **pharmaceutical waste** and they are:

- ✓ All expired pharmaceuticals
- ✓ All unsealed syrups or eye drops (expired or unexpired)
- ✓ All cold chain damaged unexpired pharmaceuticals that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines)
- ✓ All bulk or loose tablets and capsules.
- ✓ All unsealed tubes of creams, ointments, etc. (expired or unexpired).

Special disposal is needed for the following:

- Controlled substances; e.g. narcotics, psychotropic substances
- Anti-infective drugs
- Antineoplastics
- Cytotoxic anti-cancer drugs, toxic drugs
- Antiseptics and Disinfectants

All other pharmaceuticals should be sorted by dosage form:

- **solids, semi-solids and powders**

✓ tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories, etc.;

- **liquids**

✓ solutions, suspensions, syrups, etc.

✓ ampoules;

- **aerosol canisters**

✓ including propellant-driven sprays and inhalers.

3.6 Hazardous or potentially hazardous non-pharmaceutical materials

- All non-pharmaceutical, potentially dangerous waste such as chemicals, cleaning solutions, batteries and waste oil must be dealt with on a case-by-case basis by the hazardous waste expert.
- They must not be handled by the pharmaceutical teams unless expressly directed to do so.
- This waste requires separate and careful labeling and storage until disposal.

3.7 Recyclable material

- Waste paper, cloth, packing materials, clothes, gauze and wooden items, such as pallets, can be recycled, burned or disposed of as normal waste to a landfill.
- Plastic, metal and glass items can be reused (glassware can be given to laboratories, mechanical items given to scrap dealers), recycled (if facilities are available) or disposed of in a landfill.
- If a recycling programme exists for the reuse of such materials they can be separated from the pharmaceuticals prior to their disposal in the landfill.

4. Recommended disposal methods by sorting category

- **4.1 Solids, semi-solids and powders**
- Anti-infective drugs, controlled drugs and antineoplastics
- If it is not possible to return these to the manufacturer or adequate incineration is unavailable then encapsulation or inertization is recommended before discharge to a landfill
- Anti-infective drugs and antineoplastics are encapsulated to delay release to the environment and avoid high concentrations.
- Controlled drugs should be immobilized under supervision of the pharmacist, the police or a judicial representative, depending on the local regulations.

Other drugs

- Small quantities of solid and semi-solid pharmaceuticals, typically not more than 1% of the total daily waste, can be disposed of directly in a landfill with large volumes of municipal solid waste, if no other suitable method is available.

- The pharmaceutical solid waste should be disposed of at the base of the working face of the landfill and covered immediately by fresh municipal waste. Security measures to prevent scavenging should be in place.

- Pharmaceuticals classed as readily biodegradable organic material in the solid or semi-solid form, e.g. vitamins, can also be disposed of in a landfill.

Contd...

- Large quantities of solid and semi-solid pharmaceuticals are best destroyed by high temperature incineration
- Medium temperature incineration widely practiced for solid form pharmaceuticals, provided that the pharmaceuticals are "diluted" in large quantities of municipal waste.
- Many countries however do not have access to either high or medium temperature incineration plants, and the use of the encapsulation method represents an acceptable

4.2 Liquids

Pharmaceuticals with no or low toxicity

- Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer.
- Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed of in sewers.

Other liquid pharmaceuticals

Except controlled drugs, anti-neoplastics or anti-infective drugs

- Small quantities of other liquid pharmaceuticalscan be flushed into sewers.
- If there are no sewers first diluted with large volumes of water and poured into large watercourses, providing they are immediately dispersed and diluted by the flowing river water.
- Liquid pharmaceutical waste may be disposed of using the cement encapsulation procedure, high temperature incineration or in cement kilns
- It is not acceptable to discharge liquid pharmaceuticals, diluted or not, into slow moving or stagnant surface waters.

4.3 Ampoules

- These can be crushed on a hard impermeable surface using a stout block of wood or a hammer.
- The crushed glass should be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill.
- The liquids released from the ampoules should be diluted and disposed
- Ampoules should not be burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator. Melted glass will also clog up the grate of a furnace or incinerator if the operating temperature is above the melting point of glass.

- **Ampoules of anti-neoplastics or anti-infective drugs must not be crushed and the liquid discharged to sewers.**

4.4 Anti-infective drugs

- Anti-infective drugs should not be discarded in an untreated form.
- They are unstable and are best incinerated, and if that is not possible encapsulated or inertized.
- Liquid anti-infective drugs may be diluted in water, left for two weeks and disposed to the sewer.

4.5 Controlled substances

- Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations.
- Such substances must not be allowed into the public domain as they may be abused.
- They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

4.6 Anti-neoplastics

- Segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. Safely packaged and returned to the supplier for disposal.
- Must be destroyed in a two-chamber incinerator which operates at a high temperature of at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment.
- Should never be disposed of in a landfill other than after encapsulation or inertization.
- May only be discharged in a sewerage system after chemical decomposition & must not be discharged untreated into surface water drains or natural watercourses.

Special treatment for anti-neoplastics

- For antineoplastics drums should be filled to 50% capacity with drugs, after which a well-stirred mixture of lime, cement and water in the proportions of 15:15:5 (by weight), should be added and the drums filled to capacity.
- The drums should then be sealed by seam or spot welding and left to set for 7 to 28 days.
- This will form a firm, immobile, solid block in which the wastes are relatively securely isolated.
- The drums are then placed at the working face of a landfill which has been lined with an impermeable layer of clay or membrane.

Antineoplastic drug disposal

- **Methods of disposal:**
- 1. Return to supplier
- 2. High temperature incineration
- 3. Waste encapsulation

- **Methods of disposal of antineoplastics *not* to be used**

✓ Low and medium temperature incineration

✓ dIsposal to sewers and water courses

✓ Directly to landfill

4.7 Disinfectants

- Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage.
- Small quantities of diluted disinfectant may be disposed of by discharge to a sewer providing the operation is supervised by a pharmacist and the quantities are strictly controlled to set limits.
- The guideline control proposed is 50 litres total per day, with the disposal spread over the whole working day.

Contd...

- If possible, disinfectants should be used, for example for toilet cleaning in hospitals.
- Some disinfectants with strong bactericidal and antiviral activity, such as Lysol (50% cresylic acid), may have an expiry date.
- If this date has passed, the material can still be used for general disinfection purposes at an appropriate dilution decided by a pharmacist, or disposed of in a chemical waste disposal facility or a cement kiln.

4.8 Aerosol canisters

- Disposable aerosol canisters and inhalers should not be burnt or incinerated.
- High temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator.
- Provided they do not contain poisonous substances they should be disposed of in a landfill, dispersed among municipal solid wastes.

Conclusions of Presentation

- Treatment of pharmaceutical waste is important from health and safety related properties.
- Disposal of solid pharmaceutical waste and elimination of the emissions from incinerator operations are very important to protect the land, water bodies and atmospheric environment
- Landfills are most popular final disposal technique
- Proper design of incinerators and landfills is important to fulfil the regulatory requirements
- Proper planning, design, and operation are the key points involved in the disposal of pharmaceutical waste

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COUNTERTHINK

FACT: PHARMACEUTICALS DESTROY AQUATIC ECOSYSTEMS.

Thank you..