investigational Drug

Any drug or placebo which is being tested or used as a reference in a clinical trial, including a registered drug used in a different formulation, or used for an unapproved indication, or used in doses outside the approved range is called as investigational drugs. An investigational drug can also be called an experimental drug and is being studied to see if disease or medical condition improves while taking it. Hospitals and other healthcare agencies are the major centers for clinical studies with investigational drugs and pharmacists in these institutions should be involved with policies and procedures for the safe and ethical use of these drugs

Principles

Hospitals are the primary centers for clinical investigations on drugs. By definition these are drugs which have not yet been released by the Federal Food and Drug Administration for general use. Since investigational drugs have not been certified as being for general use and have not been cleared for sale in interstate commerce by the Federal Food and Drug Administration, hospitals and their medical staffs have an obligation to their patients to see that proper procedures for their use are established.

Procedures for the control of investigational drugs should be based upon the following principles

1. Investigational drugs should be used only under the direct supervision of the principal investigator who should be a member of the medical staff and who should assume the burden of securing the necessary consent.
2. The hospital should do all in its power to foster research consistent with adequate safeguard for the patient.
3. When nurses are called upon to administer investigational drugs, they should have available to them basic information concerning such drugs- including dosage forms strengths available, actions and uses, side effects and symptoms of toxicity etc.
4. The hospital should establish, preferably through the pharmacy and therapeutics committee, a central unit where essential information on investigational drugs is maintained and whence it may be made available to authorized personnel.
5. The pharmacy department is the appropriate area for the storage of investigational drugs as it is for all other drugs. This will also provide for the proper labeling and dispensing in accord with the investigator's written orders

Classification

I. **On the basis of hospital research programmed the investigational drugs**

(a) **Class A**: should contain all investigational use drugs that are in a preliminary experimental stage. The use of drug in this category is usually restricted to the principal investigator.

(b) **Class B**: should consist of investigational use drugs which have passed through the preliminary research stage. Usually, drugs in this category are supplied to the department of pharmacy by the principal investigator and are dispensed only upon his written prescription.

(c) **Class C:** is limited to drugs approved by the USP, NF or passed by the Federal FDA for commercial distribution. Drugs in this category may be used within the hospital or its clinics if the physician complies with some specific procedures.

(d) **Class D**: drugs are preparations which have been accepted for use in the hospital and are listed in the hospital formulary.

I. On the basis of hospital pharmacy operation

(a) General - An FDA-approved drug which as recommended as essential for good patient care with a well established usage, once accepted, may be prescribed by all members of the attending and house staff.

(b) Conditional – Certain drugs may be approved for a conditional period of trial. A drug approved by the FDA for general use, but which the Committee wishes to evaluate for given period before final consideration, may be prescribed by all members of the attending and house staff.

(c) Investigational – Drugs which are not approved by the FDA for use other than under controlled clinical settings must be approved by the Research Advisory Committee. A protocol of any study involving drugs must be submitted to the pharmacy.

Control of Investigational Use of Drugs

All investigational drugs should be registered with the Pharmacy and Therapeutics Committee. This may be accomplished by a letter from the principal investigator, which provides the following information:

01. New drug number 02. Generic name 03. Manufacturer
04. Chemical Name 05. Proprietary name 06. General Chemistry
07. Pharmacology 08. Toxicology 09. Dose Range
10. Method of Administration 11. Antidote 12. Therapeutic use.

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In order to control the use of investigational drugs many pharmacists have developed various forms which may be used to disseminate the above information on an investigational use drug to the various staff doctors and nurses. These forms are usually titled:

Physician's Data Sheet on Investigational Drugs

Nurse's Data Sheet on Investigational Drugs

Pharmacist's Data Sheet on Investigational Drug

(a)Physician's Data Sheet

The Physician's data sheet must contain following information:

1. Name of the Investigational Drugs:
2. Manufacturer or other source:
3. Strength and Form of Investigational Drug:
4. Amount Received:
5. Date Received:
6. Control or Batch #

7. Pharmacologic and Therapeutic Properties, Dosage, Precautions:
8. Arrangements which have made for its administration
9. Signature of Investigator

(b)Nurse's Data Sheet

The Nurse's data sheet must contain following information:

1. Name of the Investigational Drugs:
2. Manufacturer or other source:
3. Strength and Form of Investigational Drug:
4. Pharmacologic and Therapeutic Properties, Dosage, Precautions to be observed:
5. Arrangements which have made for its administration
6. Signature of Nursing In-charge

(c)Pharmacist's Data Sheet

The Pharmacist's data sheet must contain following information:

1. Investigational Drug:
2. Manufacture:
3. Chief Investigator:
4. Date:
5. Physician
6. Patient
7. Rx.#
8. Amount
9. Ward
10. Signature of Chief Pharmacist

Advisory Committee for Investigational Use of Drugs

The Pharmacy and Therapeutic Committee (PTC)

FDA advisory committee system

(a) The Pharmacy and Therapeutic Committee (PTC)

The PTC is a group of persons which formulate policies regarding evaluation and therapeutic use of investigational drugs. This committee is composed of Physicians, Pharmacist, and other health professionals with the inclusion of the medical staff. It looks after the safety in handling and administering the investigational drug. It also plays a vital role in monitoring adverse drug reaction. Every case of adverse drug reaction is first reported by the attending physician to the chairman of the PTC. The PTC interacts with various government bodies like drug technical advisory board (DTAB), Central Drug Research Institute (Lucknow), Drugs Controller General of India, All India Institute of Medical for consultation for adverse drug reaction of investigational drugs

(b) FDA advisory committee system

FDA advisory committee provides technical assistance related to the development and evaluation of investigational drugs, biologics, and medical devices. It also lends credibility to its decisions and decision-making processes, and provides a forum for public discussion of certain controversial issues. The primary role of FDA technical advisory committees is to provide independent expert scientific advice to the agency in its evaluation of investigational drugs any stage of consideration by the agency. A related role is to advise the agency on general criteria for evaluation and on broad regulatory issues that are not related to a specific product