

The Role of Searching and Evaluating the Literature to Ensure Patient Safety in Clinical Research: Practices and Protocols

***A Drug Information Service/Pharmacy
Perspective***

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Institutional Review Board (IRB)

◆ Purpose of the IRB is to

Review proposed research and determine if the rights and welfare of human subjects involved are adequately protected

Institutional Review Board (IRB)

- ◆ **Serves as an independent assessor of risks and benefits of research on human subjects**
 - **Ensure that patients can make an informed decision regarding their participation**
- ◆ **Motivation of study subjects must not obscure their consideration of the risks**

Risk Assessment Considerations

- ◆ Virtually impossible to make judgment of benefits versus risk objectively
- ◆ Types of risks: physical, psychological, social, legal, financial
- ◆ Risk considerations
 - Nature
 - Probability
 - Magnitude

Risk Assessment Considerations (Cont)

- ◆ **Ethical dilemma – balancing personal risk versus subject and/or societal benefit**
- ◆ **Assessment of risk**
 - **Important responsibility of investigator & the IRB**
 - **are estimates of the probability of harm or benefit reasonable**
 - **Requires thoroughness in gathering and critically evaluating available information**

Role of the Drug Information Service (DIS) and Pharmacist

- ◆ **Drug Information Centers/Services provide a variety of services directed at ensuring appropriate drug therapy in patients**
 - Providing drug therapy consultations
 - Monitoring adverse drug reactions
 - Assisting in development of institutional drug formularies and clinical pathways
- ◆ **Staffing**
 - Specialists with Pharm.D. degree and at least 1 year of postgraduate specialty training
 - Pharm.D. students and postgraduate residents

Role of the DIS and Pharmacist (cont)

- ◆ A DIS usually will have a close working relationship with medical librarians
- ◆ Training of pharmacists includes specific coursework in the areas of
 - Sources of drug information
 - Tertiary references
 - Indexing and abstracting sources & online databases
 - Miscellaneous sources
 - Biostatistics and drug literature evaluation

Role of DIS in Institutional Formularies

- ◆ **Pharmacy and Therapeutics (P&T) Committee responsible for selecting drugs available in the institution (the formulary)**
- ◆ **Typical process**
 - **Physician requests that a new drug be added to the formulary; rationale for the request is provided**
 - **DIS or pharmacist prepares a comprehensive written monograph evaluating the safety and efficacy of the drug in comparison to other similar drugs**

Role of DIS in Institutional Formularies

◆ Typical process (cont)

- Drug monograph is used by the P&T Committee as a basis for discussion and decision-making

◆ Similar process likely not feasible in the IRB/ research setting based on volume of research proposals submitted

Typical DIS Search Strategies for Assessing Risk

- ◆ Approach will vary to some extent based on whether dealing with
 - Investigational drugs or
 - Approved drugs for nonapproved uses
- ◆ General resources
 - Approved product labeling
 - Basic pharmacology or clinical drug references
 - Specialty texts (i.e., Myler's Side Effects of Drugs)

Search Strategies for Assessing Risk (cont)

◆ Online Indexing & Abstracting Databases

- MEDLINE
- Pre-Medline
- SciSearch (Science Citation Index)
- Current Contents
- EMBASE (Excerpta Medica)

Search Strategies for Assessing Risk (cont)

◆ Miscellaneous Resources

- Reactions (ADIS)
- FDC Reports (“The Pink Sheet”)
- FDA (MedWatch) data
- Interlibrary Loan

Search Strategies for Assessing Risk (cont)

◆ Systematic Reviews

- involves the application of scientific, methodologically rigorous strategies to the retrieval, critical appraisal, and synthesis of all relevant evidence from studies that address a specific clinical question**

◆ Sources of systematic reviews

- Cochrane Library**
- Agency for Healthcare Research and Quality (AHRQ)**
- Database of Abstracts of Reviews of Effectiveness (DARE)**