

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

Johns Hopkins' recent experience with issues of patient safety in clinical research reinforced the importance of a thorough, current knowledge of the peer-reviewed literature in ensuring the safety of individuals who participate in clinical research. The process by which this is achieved has been, in most cases, left undefined. Institutions increasingly have offered investigators direct access to online literature resources, and as a result fewer work with expert searchers from their affiliated libraries. Investigators have faced the challenge of not only mastering the literature, but also the online tools that provide access to that literature. Moreover, the projected increase in funded clinical research based on NIH current and projected appropriations has generated a corresponding increase in the volume of proposed research to be reviewed and monitored by institutional review boards [IRBs]. Oversight would be enhanced in these circumstances with defined processes and procedures to ensure that a thorough review of the literature and an unbiased evaluation of risk has been completed prior to approving and undertaking clinical research. The need for collaboration and pooling of expertise has emerged as important to a successful and complete review of all available data. Using clinical research with drug interventions as a case in point, this panel will discuss these issues from the point of view of several contributing disciplines: research administration, librarianship, drug information services, and clinical investigation.

The panel will open with a brief overview of current practices by institutions and investigators in searching and evaluating the literature prior to and during clinical investigations. For example, Johns Hopkins University, at the request of the Vice Dean for Research, Chi Dang, in July of 2001, formed an ad hoc group to “develop a practical standard for literature searches with specific reference to adverse events”. In an effort to create standards for an adequate and comprehensive literature search of drug safety, an internal JHU multidisciplinary group was assembled. The resulting protocol published in January 2002, which is collaborative in nature, is currently being tested. Other models include an emerging profession called an ‘informationist’, and the deployment of subject specialists that function as information services ‘liaisons’ to medical disciplines. These and other models currently being used to ensure the incorporation of current published data and practice into clinical research will be described.

After a brief overview by the panel organizer, Kate Oliver, the panelists will provide short descriptions of efforts within their own professions and institutional functions, focusing on their success, short-comings, and suggestions for improvements. Panelists represent professions and functions that offer expertise that contribute to a collaborative model for drug literature review and evaluation.

Panel Organizer

Kathleen Burr Oliver, MSLS, MPH, Associate Director, Welch Medical Library, Johns Hopkins University, Baltimore, MD, will provide a brief overview of the issues and currently applied practices and models.

Panel:

Paul Lietman, M.D., Ph.D., Professor, Johns Hopkins University School of Medicine, Baltimore, MD, who chairs an IRB at Johns Hopkins School of Medicine, will discuss the role of the literature search and evaluation from the perspective of the institutional review board, and the efforts of Johns Hopkins to define a protocol to ensure an adequate and comprehensive review of the literature prior to clinical research.

Terry Ann Jankowski, MLS, AHIP, Information Management Librarian, Health Sciences Libraries, University of Washington, Seattle WA, will describe her work with investigators and the IRB at the University of Washington.

Leroy C. Knodel, Pharm.D., Director, Drug Information Service, Department of Pharmacology, University of Texas Health Science Center at San Antonio, Texas, will describe the role of the drug information service in clinical research at the University of Texas, San Antonio.

Lee A. Fleisher, M.D., Associate Professor of Anesthesiology, Vice Chair for Clinical Investigation, Clinical Director of the Operating Rooms, Joint Appointments in Medicine, Biomedical Information Sciences and Health Policy & Management, Johns Hopkins Medicine will bring recent and relevant experience in clinical practice and clinical trial literature review to the discussion.