The congruence of the adherence measures was classified as high, medium or low. This allowed a comparison of the congruence between categories of adherence measures. **RESULTS:** Eighty-four studies were identified that met the inclusion criteria. The distribution of self-report measures were: interview (n = 48), questionnaire (n = 22), diary (n = 14). The non-self-report methods were: electronic measures (n = 29), pill count/canister weight (n = 22), biological assays (n = 17), claims (n = 10) and third-party opinion (n = 6). There was substantial variation in the pattern of congruence across the different types of self-report measures. Interviews had the poorest congruence with other measures of adherence (only 15 of 48 comparisons found high congruence). Diaries and Questionnaires were more likely to exhibit high congruence with other measures (10 of 14 studies, and 12 of 22 studies, respectively). Only 5 of the 29 studies involving electronic measures reported high congruence with self-reports, although the other non-self-report measures were often highly congruent with self-report (32 of 53 studies). **CONCLUSION:** The congruence of self-report and other measures of medication adherence varies widely based upon the type of measure.

**PATIENT SAFETY RESEARCH: A DISCUSSION OF TERMINOLOGY, PROPOSED DEFINITIONS, AND A CONCEPTUAL MODEL FOR ADVERSE EVENTS INVOLVING MEDICAL DEVICES**

**Bright RA**, Kaye R, Samore M

1Food and Drug Administration, Rockville, MD, USA; 2University of Utah, Salt Lake City, MD, USA

Terminology and conceptual causation models in patient safety research arose separately in the fields of human factors, epidemiology, engineering risk management, and drug safety; they are confusing and conflict with one another. Much of the terminology perpetuates undesirable concepts, such as implicit determination of causation, and poorly fits an important arena, safety of medical devices. **OBJECTIVES:** To review and propose terminology and to propose a conceptual model for interpreting research and designing interventions to reduce confusion and enhance understanding and communication in this area. **METHODS:** We systematically reviewed the terminology used in scientific literature, discussed the meanings, and made proposals. We also reviewed existing models and proposed one that enhances the models that are in the literature. **RESULTS:** We propose a set of terms and definitions for “error,” “hazard,” “adverse event,” “preventable adverse event,” “potential adverse event,” and “risk.” The terms and their definitions are as neutral as possible with respect to “blame issues” such as “responsibility,” “negligence,” and “intentionality.” We also proposed a model that builds on these ideas and on Rothman’s “causal pie” concept. The concepts allow explicit recognition of partial, rather than full, understanding of hazardous situations. **CONCLUSIONS:** The proposed terms, definitions, and model could clarify thought, research design and interpretation, the process of designing and evaluating patient safety interventions, and communication between interested parties, including researchers, laypersons, healthcare providers, and risk managers.

**INTERNET-BASED PATIENT REGISTRIES IN COMMUNITY PRACTICE**

**Sherwood AD**, Walt JG

1MedNet Solutions, Minnetonka, MN, USA; 2Allergan, Inc, Irvine, CA, USA

**OBJECTIVES:** To assess the level of user acceptance for an Internet-based methodology for collecting patient outcomes data from an observational multi-site postmarket study gathering data from community based ophthalmic practices. **METHODS:** The study coordinator at each participating site (N = 41) was issued an ID & Password for logging onto the secure and confidential site. Training of the study coordinators on how to use the site and patient confidentiality considerations took about 30 minutes. Two sets of questions were being asked: Physician Questions (8 baseline, 4 followup) and Patient Questions (9 baseline, 18 followup). Patients were followed for approximately six months. A small honorarium in return for completing the study documents was paid. Both glaucoma specific clinical & QOL data was collected and analyzed. **RESULTS:** Forty-one sites registered 360 patients for the study. Final follow-up data was entered on 318 of the 360 registered patients (88%) using the web-based case report forms. Eighty-seven percent (36/41) responded to a user survey and all respondents 100% (36/36) felt the system was simple and easy to use. Several users were so enthusiastic they gave text quotes of additional positive praise on the survey. Many indicated they actually enjoyed participating. **CONCLUSIONS:** Internet-based post-market studies are a promising methodology for the benefit of both the study sponsor and participating sites.

**EVALUATING RETROSPECTIVE STUDY POSTERS PRESENTED AT THE ISPOR 7TH ANNUAL CONFERENCE**

**Patel VD**, Setyawan J, Nichol MB

University of Southern California, Los Angeles, CA, USA

**OBJECTIVE:** Evaluate the quality of retrospective study design posters presented at the ISPOR Seventh Annual Meeting using the criteria published by the ISPOR Task Force on Retrospective Databases. **METHODS:** Of the 337 posters presented at the conference, we had access to 133 (39%) from on site collection or the ISPOR website. These 133 posters were categorized into one of 5 cate-
categories: Prospective, Retrospective, Modeling, Quality of Life or Other. A total of 41 retrospective posters were identified through this process, and all were evaluated using a slightly modified ISPOR retrospective checklist (4 criteria were separated into components, yielding a total of 14 points). This checklist helps evaluate the appropriateness of the database, the study design, and the data analysis procedures used. Posters were evaluated by three reviewers to assess compliance with the criteria.

RESULTS: The median score was 7 points (out of 14 criteria). The highest score was 11 points and the lowest score was 5 points. More than three-fourths of the posters did not confirm the validity of their data (criterion 2), inclusion/exclusion criteria (criterion 4b), sensitivity analysis for controversial variables (criterion 5b), and the possibility of alternative explanations (criterion 10b). More than half of the posters additionally failed to acknowledge the study design limitations (criterion 3b), describe the method and/or rationale for costing (criterion 6), and control for confounding variables (criterion 7). CONCLUSION: Most of the posters in this convenience sample ranked at the midpoint of the expanded ISPOR checklist. Researchers should pay close attention to the ISPOR checklist when preparing their poster presentations to assure consistently good research practices.

BEST PRACTICES: EVALUATING MODELING RESEARCH AT ISPOR USING BMJ AND ISPOR GUIDELINES
Setyawan J, Patel VD, Nichol MB
University of Southern California, Los Angeles, CA, USA

OBJECTIVE: To evaluate whether the modeling posters presented at the 2002 ISPOR Seventh Annual International Meeting met the standard of good research practice criteria established by British Medical Journal (BMJ) and ISPOR. METHODS: Posters presented at the meeting were collected onsite or from the ISPOR website. Of the total 337 posters presented, 133 posters (39%) were evaluated. Of the 133 posters collected, 26 were classified as modeling. Nine (9) modeling posters were excluded because they focused exclusively on the denominator or numerator. The remaining 17 posters were evaluated in 3 major sections: a) study design (7 items for BMJ; 3 for ISPOR); b) data validity (14 items for BMJ; 13 for ISPOR); c) analysis and interpretation (14 items for BMJ; 23 for ISPOR). RESULTS: More than half of the posters satisfied 75% or more of the ISPOR and BMJ criteria for study design, and only 5 failed to satisfy at least 50% of the study design criteria. Only six posters satisfied 50% or more of the BMJ data validity criteria, and none of the posters satisfied 50% or more of the ISPOR data validity criteria. More than half of the posters satisfied 50% or more of the BMJ and ISPOR criteria for analysis and interpretation. Posters were slightly more likely to satisfy the BMJ, rather than ISPOR criteria for data validity. Overall, the 17 posters met 51% (18/35) of the BMJ criteria and 46% (18/39) of the ISPOR criteria. CONCLUSIONS: The number of posters reviewed and the number of evaluators limit this study. Reviewed posters revealed satisfactory performance in the study design elements of the ISPOR and BMJ guidelines, but could be improved in data validity and analysis. Generally, the posters performed better when rated using the BMJ rather than the ISPOR guideline.

PHARMACOEPIDEMIOLOGY: A REVIEW OF ITS EMERGING ROLE IN OUTCOMES RESEARCH
Richard L
Heron Evidence Development Ltd, Stevenage, Hertfordshire, United Kingdom

Pharmacoepidemiology is defined as the application of epidemiological reasoning methods and knowledge to the study of the uses and effects (beneficial and adverse) of drugs in human populations. OBJECTIVES: The purpose of this paper is to review the emerging role of pharmacoepidemiology in outcomes research. METHODS: This review has been based on a systematic literature search using Medline (PubMed), including the abstracts of the International Conference of Pharmacoepidemiology since 1990, and a review of core texts recommended by the International Society for Pharmacoepidemiology (ISPE). RESULTS: Three core functions were highlighted by review of the literature. The major role was found to be in the field of pharmacovigilance and its function in phase IV clinical trials or postmarketing surveillance. This was reflected by the predominance of pharmacovigilance abstracts accepted by the ISPE—90% (201/223) of abstracts in 1990 and 72% (222/309) in 2001. Pharmacovigilance, the process of identifying and responding to drug safety issues during phase IV of drug development, is a key requirement of many drug regulatory authorities, including the FDA. Pharmacoepidemiology was also found to play a role in drug utilisation review studies and decision analytic modeling, although its use was found to be less substantial, constituting the balance of the accepted abstracts. CONCLUSION: Although pharmacoepidemiology has mainly been used in the field of pharmacovigilance, its use in decision analysis and drug utilisation review was found to be on the increase.

OPTIMIZING CLINICAL EFFECTIVENESS THROUGH ACTUARIAL MODELING IN HOSPITALS

OBJECTIVES: Current data support the use of low molecular weight heparin (LMWH) in lieu of unfractionated