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Pitfalls of Health Writing: The Stories Behind the Studies

By Jane Neff Rollins

Journalists Jeanne Lenzer and Rob Waters presented the "Pitfalls of Health Writing" session at the AHCJ annual conference. Lenzer showed attendees how to critique published results about clinical trials involving new drugs, after which Waters concentrated specifically on critique of research about psychiatric drugs.

In searching for the story behind the story, "reading the methods section can pay off," Lenzer stated. She highlighted the need to pay attention to the construction of control groups, lead-time bias, and selection bias. Lenzer encouraged reporters to evaluate the implications of the inclusion and exclusion criteria for trial participants, particularly demographic characteristics (e.g., socioeconomic status) and history of medication use.

Lenzer also alerted attendees to the technique of cut-point optimization, in which data from groups of patients who did not respond to a study drug are omitted from the report. She summarized techniques such as run-in (all patients take the study drug for a short time to see if they tolerate it) and wash-out (patients stop taking their existing prescription drugs just before the trial begins). If either technique is done prior to randomization of patients to treatment or control groups, it can affect the interpretation of whether a drug is effective and safe or not.

Journalists also learned how to compare graphically the placebo group's response to a drug to that of the treatment group, thus illustrating that much of a drug's purported effect can be ascribed to the placebo effect. Waters subsequently gave more details on both of these issues.

Waters' focus on mental health and psychiatric drugs was particularly relevant because drugs for psychiatric and neurological indications were the third, fourth, and fifth top-sellers in the U.S. in 2004. "Psychiatric drug trials are just the ultimate in spin; it's mind-boggling," he said.

Waters alerted reporters to the possibility that a clinical trial may report combined endpoints. If a drug decreased the incidence of stroke, but also increased all-cause mortality, a report may lump both results into one statement such as: "Drug X reduced morbidity and mortality."

In describing the importance of statistical power, the ability of a clinical trial to discern a positive effect of a drug if such an effect exists, Lenzer used a particularly useful analogy. If you throw a set of two dice twice and get snake eyes once, you can't assume that the probability of getting snake eyes is 50 percent — your gambling "trial" of 2 events is underpowered.

Waters pointed out that the results of drug trials submitted to the FDA are powered adequately to assure approval of a psychiatric drug, but are not powered sufficiently to determine if a new drug may be associated with increased risk of suicide. This issue is particularly important in light of the FDA's recent request that 14 manufacturers of anti-seizure drugs re-examine the clinical trial data to determine if such medications may be associated with increased risk of suicidal thoughts or behaviors.

Waters also highlighted the importance of examining the extent to which researchers may receive financial support from pharmaceutical manufacturers. The list of investigators' conflicts of interest for the Trazedone trial was so long that the journal put it on its Web site as an appendix for lack of space in the printed version. Patient advocacy groups also receive financial support from pharmaceutical manufacturers.

According to Waters, "Even academic psychiatrists say 'I don't know what to believe, I don't know whom to trust.'"

The speakers both implied that all pharmaceutical manufacturers manipulate the data reported from clinical trials so much that drugs don't work at all. But there is another story behind the story. An otherwise healthy 75-year-old woman with osteoarthritis and no family history of heart disease, whose painful, swollen hands interfere with activities of daily living may be willing to take a COX-2 inhibitor knowing that her risk of heart attack may double. Similarly, if an atypical psychotic medication is the only drug that stills the voices in a schizophrenic patient's head, then that patient may be willing to take the risk of extrapyramidal symptoms such as twitches or facial tics.

In seeking justifiably to publicize safety issues that drugmakers may try to spin out of existence, reporters must still accord fair balance to their stories and cover the clinical implications of not treating a given disease or disorder.

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