CEIPE THE CONSORTIUM OF EVIDENCE-INFORMED PRACTICE EDUCATORS

The Savvy Practitioner

A bulletin for practitioners and teachers of informed-based practice.

Target audience this issue:

✓ ***Faculty in general***

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How to Read an Article about Harm

Consider this question: how would you test the idea that smoking causes cancer? The best way to do so would be to develop a clinical trial in which half of the participants were required to smoke three packs of cigarettes per day for five years while the other half did not smoke at all. You could then see if there were differences in the rate of lung cancer between the two groups. But, of course, this is not ethical.

Given that we cannot use clinical trials to answer such questions, we can use other designs, including both a case-control study design and a cohort design. In a case-control study we would look in the past medical records and exposures of cases (those with lung cancer) and controls (those without) and would find that some in each group were heavy smokers while others were not. We could then calculate the difference in rates of cancer between the two groups. In such case, we would end up with an ***odds ratio (OR)***; that is, the odds that exposure to smoking leads to lung cancer. In a cohort study, we would follow people forward in time while allowing them to live their life. None have cancer at the beginning of the study. We would find, years down the road, that some in both groups were heavy smokers while others were not, and again we could calculate the difference in rates of cancer between the two groups. In this case, we would end up with a ***risk ratio (RR)***.

Risk is associated with disease incidence; that is, the rate of newly diagnosed conditions in a population. In a case-control study, we are starting with people who already have the condition of interest; therefore, we cannot calculate risk (which requires us to newly diagnose a disease), and instead we look at odds. In other words, relative risk compares the outcomes of the entire pool of subjects who were exposed to a risk factor. They also track all of the patients in the pool without the risk factor. They track everyone so we can get a fair comparison. Odds ratios only look at part of the exposed pool—those who had the bad outcome. It doesn't take into consideration those who were exposed and had a good outcome. So the data set is incomplete.

Ioannidis (2005) suggests that the larger the RR or OR, the greater the chances that an association between exposure and outcome is meaningful. He writes "Thus research findings are more likely true in scientific fields with large effects, such as the impact of smoking on cancer or cardiovascular disease (relative risks 3–20), than in scientific fields where postulated effects are small, such as genetic risk factors for multigenetic diseases (relative risks 1.1–1.5)."

Small RRs or ORs may reflect a small but real risk. On the other hand, they may simply be the result of the "noise" introduced by all of the potential

Help your students understand how to read a paper assessing a harm paper.

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errors inherent in observational studies—less likely "truth" and more likely a statistical illusion.

When we read an article about harm, we need to understand the specific study design being used. While clinical trials are best, they often cannot be conducted. Cohort studies are stronger than case-control studies, since they allow us to calculate the true disease rate in a group. But in studies of harm, other questions to look at while reading are to ensure that the exposures and outcomes in both groups were measured the same way, that follow-up was long enough, that the exposure precedes the adverse outcome, and that the association between exposure and outcome is strong.

It is important to understand that risk and odds ratios do not tell you how frequently a problem occurs, only that the effect occurs more or less often in the exposed group compared to the unexposed group. This can then tell you whether or not to recommend the patient stop the exposure. Once we know, for example, that smoking is associated with a higher rate of cancer, we can advise patients to stop smoking.

Searching for harm studies

It is important for students and faculty to know how to search for these types of studies. The category of HARM is composed of two, sometimes three, main topics: risk factors, side effects, and etiology. Harmful *risk factors* are usually thought of as any factor in an individual's behavior (e.g., diet, lifestyle), exposures (e.g., asbestos, air quality), or genetic makeup that makes them *more susceptible to disease or injury*. This differs from risk factors that are present in a patient *who already has a disease or condition* which might lead to a worse outcome than otherwise would have been the case (this type of question falls into the realm of prognosis). Etiology usually refers to the causative agent of a disease or condition.

When searching PubMed using the ***clinical queries*** filter, you should generally select ***etiology*** or ***prognosis*** depending on which seems most appropriate. In MEDLINE searches using the ***clinical queries*** filter, select ***causation*** or ***prognosis***. You can also enhance your search string by adding *AND (cohort OR case control)* to the end of it.

For additional information on harm, please see http://www.cche.net/text

Why Pie?

Whether you are a clinician or a classroom faculty, the biannual PIE conferences afford you special training to enhance your skills in finding, assessing, and understanding research as it applies to the discipline you are teaching or the patients that you are seeing. The program provides opportunities to work with peers in McMaster's-style small learning groups to refine your ability to integrate these important evidence-informed practice skills into your teaching.

References

Ioannidis J. Why most published research findings are false. PLoS Medicine www.plosmedicine.org 0696 August 2005, Volume 2, Issue 8e124