What is evidenced based practice?

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According to Dr. David Sackett, evidenced based practice is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.” (Sackett D, 1996). This statement was published the same year I received my undergraduate nursing degree. I vividly remember my professors strongly championing research so that their newly hatched nurses would be critically thinking as we made our mark upon the future of patient care. So bright eyed I embarked on my career, armed with seeking ‘the best available external clinical evidence from systematic research’. But what is the best research?

The gold standard of research has been randomized controlled trials. In a randomized controlled trial (RCT), participants are randomly assigned to receive either the treatment under investigation or, as a control, a placebo or the current standard treatment. The randomization process helps ensure that the various groups in the study are virtually identical in age, gender, socioeconomic status, and other variables.

When reviewing research articles I am often struck by the potential influence. Certainly the journal accepting the research article makes an impression, their publishing standards, peer reviewed or not requirements, but I think I became a mild skeptic, or maybe a advanced critical thinker because of the classic example of The Lipid Hypothesis**.**

Developed by Ancel Keys in the 1950’s, this theory states that there is a direct relationship between the amount of saturated fat and cholesterol in the diet and the incidence of coronary heart disease. With questionable evidence, Keys’ went about writing articles and promoting this hypothesis throughout the medical world. Some of us were shunning the rise of margarine and sticking steadfastly to Julia Child’s favor ingredient, namely butter.

Meanwhile, hundreds of subsequent studies testing the lipid hypothesis found differing conclusions. Despite the lack of evidence, Keys’ notion took off throughout the healthcare world and was fueled by the vegetable oil and food processing industries that sought to benefit from this finding. Keys fulfilled the classic bias in research- confirmation. Even today I hear my patients worrying about ingestion of fat without distinguishing between healthy and unhealthy fat sources. What an impression was made!

So the question of bias is one that I felt should be addressed to keep us thinking critically about the information we read.

In my search to understand research bias better, I ran across a website called the Catalog of Research Biases, which encourages the reader to visit often as they are adding newly identified biases “all the time”. I reviewed this list of 37 different biases and found my head swimming to think I could filter through articles with this list of potential issues confounding the results. But as I scoured the literature (ironic that I search the research for research biases) I found that though there are many names and potential pitfalls that researchers may run into in their quest to provide insight into clinical questions, three are critical and encompass many biases by another name.

Rolf HH Groenwold (2013) makes a case for grouping the many different types of biases into 3 basic categories. Despite the use of many different terms, a distinction in 3 types of bias is sufficient to describe all forms of bias within a study: information bias, selection bias and confounding. Within these categories all other identified biases are recognized. For example, 'immortal time bias', 'recall bias' and 'observer bias' are all 3 forms of information bias, and 'healthy user bias', 'channeling' and 'protopathic bias' are synonyms for confounding. Let us discuss these 3 main categories of bias to better equip ourselves to gain ‘the best out of external clinical evidence from systematic research’ as Sackett encouraged.

Information bias, otherwise known as misclassification, is one of the most common sources of bias that affects the validity of health research. It originates from the approach that is utilized to obtain or confirm study measurements. (Althubaiti 2016)

Information bias is a systematic bias of the determinant-outcome relationship through the use of incorrect information about the determinant or the outcome (or both). The clearest example is the wrong measurement of the determinant or outcome. If the measurement error of the outcome depends on the determinant, or the measurement error of the determinant depends on the outcome, this is usually referred to as differential misclassification. (Groenwold 2013) Could the work of Keys have fallen under this type of bias? I think so. He was determined to extrapolate the outcome of heart disease from the measurement of saturated fats in the diet.

Althubaiti (2016) encourages the practice of replication as a simple approach to avoiding information bias and misclassification. To practitioners it means reading several studies before making a determination. I highly recommend Cochrane collaboration reviews because they have done a lot of the work in identifying studies and grading them according to widely accepted levels of the strength of evidence, and discloses that information in their analysis. Yet they are limited to main topics of research so we still need to understand how we are arriving at good evidence.

A second category of bias in research is selection bias. Participants in research may differ systematically from the population of interest. For example, participants included in a

medication trial may be healthy young adults, whereas those who are most likely to receive the intervention in practice may be elderly and have many comorbidities, and are therefore are not representative. Similarly, in observational studies, conclusions from the research population may not apply to real-world people, as the observed effect may be exaggerated or it is not possible to assume an effect in those not included in the study.

According to Stattrek an online statistical education forum, there are 3 types of selection bias. Whoops, there goes my effort to simplify to 3 types of bias.

- **Undercoverage**. Undercoverage occurs when some members of the population are inadequately represented in the sample. A classic example of undercoverage is the *Literary Digest* voter survey, which predicted that Alfred Landon would beat Franklin Roosevelt in the 1936 presidential election. The survey sample suffered from undercoverage of low-income voters, who tended to be Democrats. Undercoverage is often a problem with convenience samples .

- **Voluntary response bias**. Voluntary response bias occurs when sample members are self-selected volunteers, as in voluntary samples . An example would be call-in radio shows that solicit audience participation in surveys on controversial topics (abortion, affirmative action, gun control, etc.). The resulting sample tends to over represent individuals who have strong opinions or tune into that particular radio program.

- **Nonresponse bias**. Sometimes, individuals chosen for the sample are unwilling or unable to participate in the survey. This can be a big problem with mail surveys, where the response rates can be very low.

To apply this in our field of CIRS, I am acutely aware that certain laboratory test results must have differing ranges for normal versus the laboratory normal ranges published. Based on laboratory range setting my understanding is that ranges are based on the previous lab results from a particular period of time. Since Dr. Shoemaker so eloquently educated those Labs- “If I send you patients from a population of CIRS patients they almost always do have low MSH, not that the new normal should be 0-40!” This indeed is a selection bias.

The 3rd bias identified by Groenwold is confounding bias in which the effect or association between an exposure and outcome is distorted by the presence of another variable. *Positive* confounding (when the observed association is biased away from the null) and *negative*

confounding (when the observed association is biased toward the null) both occur. (Penn State online Stat 507)

In research, confounding can be prevented by assigning the treatment by chance to the participants in a study: a randomized trial. In that case, the research groups are expected to be comparable in measured and unmeasured risk factors for the outcome. (Groenwold, 2013)

And on that point we have come full circle to the stated recommendations of repeatable, randomized controlled trials being the design that is most likely to avoid these three biases of research, namely information, selection and confounding.

Despite their strengths, RCTs have limitations. They can be very expensive to run. They can take many years to complete, and even then may not last long enough to assess the long-term effect of an intervention. According to Tom Freiden MD a valid ideal is “evidence-based practice,” which means implementing in clinical care and public policy interventions that are proven to work. But it’s also important, and perhaps more so, to develop “practice-based evidence,” — that is, to implement programs and rigorously document whether or not they work. (Freiden 2016)

That statement of ‘practice based evidence’ really struck me. I felt it was a good description for the hard work Dr. Ritchie Shoemaker began so many years ago in Pocomoke, MD. when he tripped over Cholestyramine as a biotoxin intervention in an effort to control diarrhea. But it takes a tenacious practitioner to move from there to today’s body of research regarding CIRS. Using both evidence based practice and practice based evidence while humbly looking at the inevitable bias that may invade, research isn’t a perfect science. Yet where would we be without it?

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