An Introduction to Risk Adjustment in Outcomes Research

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KEY POINTS . . .

Failing to control for risk factors between populations can lead to unfair conclusions about an outcome.

Direct standardization controls for a single risk factor by adjusting all of the populations to a standard population.

Indirect standardization can control for multiple risk factors and compares the observed outcomes in a population with the expected outcomes for the population.

Overview

The goal of outcomes research is to determine the effects that various health care interventions have on clinical, economic, and humanistic outcomes in patient populations. Many stakeholders, including health care providers, patients, and policy makers, utilize outcomes research studies to help guide decision making [1]. When conducted correctly, outcomes research studies can provide a great deal of information about the impact of a specific intervention on factors such as quality of life, morbidity, mortality, costs, and patient satisfaction [2].

In an ideal world, randomized control trials (RCTs) would be conducted to answer most outcomes research questions. RCTs have the benefit of randomization, which allows both known and unknown confounders to be distributed between the intervention and control groups [1,3]. This distribution of confounders makes it easier to determine the impact of an intervention on the study outcome [3]. Because of the significant cost, time, and ethical concerns associated with RCTs, it is not possible to answer all questions using this method [2]. In cases where an RCT cannot be used, an observational study may be substituted.

This article will provide both a brief introduction to some of the risk factors encountered in observational outcomes research studies and an overview of some of the techniques used to adjust for known risks. The focus of this article will be on direct risk standardization and indirect risk standardization.

Risk Factors and the Need to Control for Them

When conducting observational studies, there are inherent differences in patient populations due to a lack of randomization. These differences can include many risk factors for a specific outcome. Some of these, including age, sex, previous illness, prior treatments, and biological differences, can be controlled for in analysis [3,4]. Other factors such as geographic differences or differences in providers may also play a role in altering outcomes [1].

It is important to control for differences in known risk factors before comparing groups, so that the outcomes demonstrated in a study represent the true impact of an intervention or the true difference between populations. A failure to control for risk factors can lead to improper or unfair comparisons between interventions or patient groups. It is especially important to consider risk factors when the results of outcomes research studies are used to drive policy decisions, payments, or clinical practice [5]. Risk standardization is a technique that is often applied when determining payments and evaluating differences between populations [6].

Direct Standardization

One method used to adjust for risk factors between populations is direct standardization. In direct standardization, the rate of an outcome, such as mortality, in each intervention group or population is adjusted to a standard population. By adjusting to a standard population, one can compare how an intervention would behave with a typical rate of a risk factor instead of the observed rate in the populations [6].

To utilize this method of standardization, the risk factor must be divided into strata. Examples of risk factors that can be stratified easily are age and sex. To calculate the directly standardized rate, the sample population is broken down into N different strata and the outcome rate for the sample population is calculated for each stratum (Ri). Then for each stratum the outcome rate is multiplied by the proportion of the standard population in that stratum (Wi). The directly standardized rate represents the sum of the sample population outcome rate for each stratum multiplied by the proportion of the standard population in that stratum [2,4,7]. Once the risk factors are standardized, outcomes comparisons can be made directly between populations.

$$Directly\ Standardized\ Rate = \sum_{i=1}^{N} W_i R_i$$

While it is a powerful tool in risk adjustment, direct standardization does have >

limitations. This technique cannot account for multiple risk factors simultaneously because it involves stratifying the sample population by one risk factor. It also does not work well if some of the strata have limited observations or the sample population outcome rate is not known for a stratum. Lastly, direct standardization also makes it difficult to identify subsets of the population that have outliers in the outcome [6].

Indirect Standardization

Another technique commonly used to adjust for risk factors is indirect standardization. This method of standardization compares how the observed outcomes in a sample population relate to the expected outcomes based on the observed distribution of a risk factor. Indirect standardization requires the availability of standard population data for an outcome [6].

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Calculating the indirectly standardized rate involves calculating the observed and expected number of outcomes for a sample population. The first step is to determine the number of patients with a specific outcome observed in the study population (O). The next step is to determine the expected number of patients with that outcome (E). The expected number of patients is calculated by stratifying the study population by the risk factor and then multiplying the number of patients in each stratum (Qi) by the outcome rate observed in a standard population with stratum i. The observed number of outcomes is then divided by the expected number of outcomes and multiplied by the overall outcome rate for a standard population (R) to yield the indirectly standardized rate [6, 7].

$$Indirectly\ Standardized\ Rate = \left(\frac{O}{E}\right) * R$$

$$E = \sum_{i=1}^{N} Q_i R_i$$

The indirect standardization method has the benefit of being able to account for multiple risk factors. A multivariable probit or logit regression model can predict the probability of an outcome for a specific patient based on multiple risk factors. The sum of these probabilities can be used to estimate the expected number of patients in the sample with an outcome (E) [6,7].

While it can address multiple risk factors, this method also has some drawbacks. The indirect standardized rate compares how an intervention performed compared to expected performance based on the specific distribution of risks in the population. The indirectly standardized rate allows for comparison of a population outcome to a standard population, but it can be difficult to make direct comparisons between two populations if there are different distributions of risk factors in each population. This method of standardization is commonly used in studies evaluating expected performance and for payment purposes [6].

Conclusion

In conducting outcomes research, especially studies comparing populations, differences in risk factors for an outcome can distort the results. Multiple techniques are available to adjust for risk factors and each has its benefits and drawbacks. Direct risk standardization allows for direct comparison between groups, but can account only for a single risk factor at a time and requires knowing the sample population outcomes rate for each strata. Indirect standardization can account for multiple risk factors but is less useful for making direct comparison between different groups or populations when there are large differences in the distribution of patients in the strata. In cases where neither direct nor indirect standardization is sufficient, more advanced techniques or alternative study designs may be required.

References

[1] Berger ML, Bingefors kerstin, Hedblom EC, eds. Health Care Cost, Quality, and Outcomes: ISPOR Book of Terms. Princeton: ISPOR; 2003. [2] Gordis L. Epidemiology. Philadelphia: Elsevier/Saunders; 2009. [3] Arcà M, Fusco D, Barone AP, Perucci CA. Risk adjustment and outcome research. Part I. J Card Med 2006;7(9):682-690. [4] Iezzoni LI, Risk Adjustment for Measuring Health Care Outcomes. Ann Arbor, Mich: Healthcare Administration Press; 1997. [5] Shaya FT, Gbarayor C. Adjusting for risk and confounding in outcomes research. Expert Rev Pharmacoeconomics Outcomes Research 2006;6(2):109-110. [6] Lane-Fall MB, Neuman MD. Outcomes Measures and Risk Adjustment. Int Anesthesiol Clin 2013;51(4):10-21. [7] Standardization. Epidemiological Research Methods. Available at: https://onlinecourses.science.psu.edu/stat507/node/36. [Accessed May 10, 2017].