Using an Empirical Method for Setting Expectations in Quality Improvement Initiatives

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Research Objective: Healthcare organizations seeking to undergo or retain their accreditation status or uphold contract terms with regulatory bodies or commercial entities are usually required to demonstrate successful clinical quality improvement efforts. In most cases, the measurement design of these studies entails a comparison of proportions of two independent groups, and the results are normally reported as "the proportion of patients receiving treatment X in one measurement period compared to the proportion of patients receiving treatment X in a subsequent measurement period." Additionally, these organizations are typically required to predetermine a target outcome level (or effect size) before the study begins and report how that objective was chosen. In most cases, the expected percent improvement goal is ascertained by reviewing the results of similar studies conducted internally vis-à-vis established benchmarks, or by simply "eye-balling" the baseline level and deciding upon a reasonably achievable target. With these approaches to study design, it can be assumed that most studies generally have no more than a 50% likelihood of successfully achieving their expected outcomes. This paper proposes a simple empirical method for determining the expected effect size for the study when only the baseline value is known.

Study Design: The standard equation for determining sample size of two independent groups where the measurement variables are proportions, requires the researcher to know or estimate several formula parameters: (1) *Power* (1 - beta) estimates the probability that the study will be able to reject the null hypothesis of no improvement. In healthcare research, the norm is to set the power at 80% (beta = 0.2), (2) *Level of significance* - alpha. This value is typically set to $\alpha = 0.05$, and (3) *Effect size* refers to the difference between Proportion 1 and Proportion 2 - delta. Since the purpose of this investigation was to develop an equation to solve for effect size, the standard sample size equation was converted algebraically, to put effect size on the left side of the equation. This formula now requires the researcher to estimate sample size – N, set alpha and beta levels, and input the value for Proportion P1. The resultant value will be the expected percentage difference between two independent groups. A grid was developed with P2 levels plotted as a function of P1 levels. 4 lines were drawn based on sample sizes of 200 to 1000, holding

alpha constant at 0.05 and beta = 0.2. This grid is meant to be a simple “at-a-glance” guide for researchers to identify approximate P2 values without the need for computation.

Population Studied: Any two independent groups of subjects where proportions are compared.

Principal Findings: As expected, the difference in effect size between P1 to P2 is largely determined by the sample size. A larger N will reduce the required effect size to ensure statistical significance, thus it is imperative that the researcher set the sample size requirements before the study is conducted. This will prevent the potential for gaming of the group size to impact the outcome measure. Similarly, the level of P1 will play a role in determining the level of change expected for P2. The data indicate that effect size moves in a parabolic fashion with the highest required change in P2 occurring at 50%, and the lowest changes required are at either the 10% or 90% levels. The range of expected change in P2 varies from 3.52% (N = 1000, P1 = 90%) to 6.35% (N = 1000, P1 = 50%) illustrating the impact of P1. Similarly, the range of expected change in P2 varies from 6.35% (N = 1000, P1 = 50%) to 14.3% (N = 200, P1 = 50%), illustrating the impact of sample size.

Conclusions: The equation presented here to establish effect size provides healthcare organizations with a reliable tool to set quality improvement targets. Sample size, alpha and beta must be determined before commencement of the study, and the effect size can be estimated once P1 has been established. Depending on the level of P1, effect size can range from 3% depending on P1 level to 12% for sample sizes ranging from 200 to 1000.

Implications for Policy, Delivery, or Practice: This paper proposes a methodology for determining quality improvement targets that are mathematically derived, thus eliminating the guessing or haggling over the setting of appropriate goals. The resulting P2 estimate should be considered a minimum expected improvement target, given that it is based on pre-study established statistical levels of significance, and may not necessarily coincide with what a practicing clinician would consider to be a clinically relevant difference.

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