

# Designing a Study for Success

In this issue of the *Journal of the American Geriatrics Society*, Milisen et al.<sup>1</sup> document the effects of a nurse-led interdisciplinary intervention for the assessment, prevention, and treatment of delirium in older adults with hip fractures. The intervention, by staff nurses in consultation with advanced-practice nurses and psychogeriatricians, covers the trajectory of care from emergency room admission to 3 months after discharge. In publishing this research, Milisen et al. provide us with several exemplars of study design. These exemplars illustrate seven axioms: (1) conduct a comprehensive, historical, and interdisciplinary review of literature to support the study and its research methods; (2) develop a clear, concise, comprehensive purpose statement to guide the study; (3) use consistent terminology and order of study variables; (4) consult a statistician when designing a study; (5) use finely graduated instrument scale scoring whenever practical; (6) use parametric data analysis whenever appropriate; and (7) calculate the power of your potential sample and, if necessary, modify the study design. Each axiom and exemplar will be discussed in turn.

## ENGLE'S AXIOM 1

Conduct a comprehensive, historical, and interdisciplinary review of literature to support the study and its research methods.

Researchers often limit their review of literature to recent publications within their discipline. Although this provides cutting-edge and discipline-specific knowledge, this approach necessarily omits older studies with undiminished relevance, and the narrowness of a single disciplinary perspective may lead to "reinventing the wheel." Milisen et al.<sup>1</sup> provide a concise interdisciplinary historical review of the literature that includes seminal pioneering works by Williams et al.<sup>2,3</sup> in 1979 and 1985 evaluating the effect of nursing interventions in preventing and treating delirium of older adults with hip fractures. The Milisen et al. review of literature builds on existing scientific knowledge to support the study objectives and research methods.

## ENGLE'S AXIOM 2

Develop a clear, concise, comprehensive purpose statement to guide the study.

Researchers must carefully develop their study's purpose statement, which is the essence of the study in a single sentence. The purpose statement is a concise, clear statement of the objective of the study, the type of study, variables, sample, and setting.<sup>4</sup> It guides the subsequent design of the study, including hypotheses or research questions, sample, variables, instruments, statistical analysis, and reports, such as presentations and publications. By consis-

tently referring back to the purpose statement when writing reports, the researcher is less likely to include text that is tangential to the purpose of the study. Milisen et al.<sup>1</sup> describe the objective of their study in the abstract and text using clear concise language that guides research methods and statistical analysis. The objective of their study was "to develop and test the effect of a nurse-led interdisciplinary intervention program for delirium on the incidence and course (severity and duration) of delirium, cognitive functioning, functional rehabilitation, mortality, and length of stay in older hip fracture patients."

## ENGLE'S AXIOM 3

Use consistent terminology and order of study variables.

Researchers should also use the purpose statement to specify the hypotheses or research questions and the variables, and their order of presentation in reports. This implicitly organizes the statistical analysis and variables in tables and figures, and in the Methods, Results, and Discussion sections of reports. Variable names should be consistent in terminology throughout the report. Milisen et al.'s<sup>1</sup> Results section is meticulous in its organization and presentation of findings, using consistent variable names and order of variables. They use a logical, step-by-step analysis strategy and presentation of results consistent with their study objective.

## ENGLE'S AXIOM 4

Consult a statistician when designing a study.

Statistical power is necessary to document statistically significant findings, when appropriate. Researchers may inadvertently omit addressing ways of conserving statistical power when designing their study. They should: (1) choose instruments with finely graduated scale scoring, (2) use parametric statistics, and (3) obtain an adequate sample size. Consulting with a statistician at the *beginning* of the study design process, before data collection, helps ensure adequate statistical power.

## ENGLE'S AXIOM 5

Use finely graduated instrument scale scoring whenever practical.

The number of scale graduations used to score study instruments affects statistical significance. Whenever practical, more or finer scale calibrations are preferred over fewer or coarser calibrations. When instruments with fewer scale calibrations are used, measurement error attenuates findings toward the null value and suppresses true statistical significance.

**Table 1. Engle's Axioms for Designing a Study for Success**

1. Conduct a comprehensive, historical, and interdisciplinary review of literature to support the study and its research methods.
2. Develop a clear, concise, comprehensive purpose statement to guide the study.
3. Use consistent terminology and order of study variables.
4. Consult a statistician when designing a study.
5. Use finely graduated instrument scale scoring whenever practical.
6. Use parametric data analysis whenever appropriate.
7. Calculate the power of your potential sample and, if necessary, modify the study design.

Milisen et al.<sup>1</sup> score participants' education as continuous, the actual number of years, rather than the usual ordinal scale scoring (grade school graduate, high school graduate, college graduate). Also, Milisen et al. measure severity of delirium using the Confusion Assessment Method (CAM),<sup>5</sup> but they use three-point scoring of CAM items ("absent" scored 0; "present—mild form" scored 1; "present—severe form" scored 2), modified in consultation with the developer of the CAM, rather than the usual dichotomous scoring ("absent" scored 0; "present" scored 1). In addition, Milisen et al. use a seven-item CAM scale rather than the usual four-item CAM scale. These two refinements in scale scoring produce a CAM score ranging from 0 to 14, rather than the usual CAM score that ranges from 0 to 4. They were able to document subsequently a significant decrease in the severity of delirium using the nurse-administered intervention, whereas a study by Inouye et al.<sup>5</sup> using the usual CAM scoring did not.

#### ENGLE'S AXIOM 6

Use parametric data analysis whenever appropriate.

Data obtained from instruments with finely graduated scales should never be collapsed into coarser scales without strong reasons, such as clinical cutpoints (i.e., the absence or presence of a diagnosis). Finely graduated data can be analyzed using parametric statistics, such as *t* tests, that conserve statistical power. Analysis of coarsely graduated data may be limited to intrinsically less-powerful nonparametric statistics, such as chi-squared.

Milisen et al.<sup>1</sup> evaluate delirium using the CAM<sup>5</sup> with finely graduated scale scoring. However, for analysis they *both* use finely graduated data (0 to 14 scoring) to evaluate the severity of delirium and collapse the finely graduated data into dichotomous data ("delirium absent" scored 0; "delirium present" scored 1) to evaluate the incidence of delirium.

#### ENGLE'S AXIOM 7

Calculate the power of your potential sample and, if necessary, modify the study design.

Last of all, an underpowered sample limits the ability to document that a clinically significant difference is statistically significant. Underpowered samples may be used because of sampling constraints. The researcher may have access to a small clinical sample with limited numbers of potential study participants. There may also be time, budget, ethical, clinical, or other inflexible design constraints. To determine whether constraints compromise study power, it is useful to have: (1) historical data about the number of

available participants in your study site that meet inclusion criteria, adjusted for participant response rate, attrition, and seasonal variation, and (2) means and standard deviations of key variables documented in prior research. It may be necessary to modify the study design to obtain a larger sample, such as by modifying sample inclusion criteria. Milisen et al.<sup>1</sup> state that they had an underpowered sample for analysis of the delirium incidence hypothesis that may have accounted for their inability to document an intervention effect for that outcome variable. They further state that their study design required a sample of 317 participants for each group to identify a 10% treatment effect for incidence of delirium, but they had only 60 participants in each group because of clinical constraints.

In summary, the article by Milisen et al.<sup>1</sup> contains several exemplars for designing a study for success. It is useful to collect exemplary articles for future reference. Exemplars may include wording of hypotheses and research questions, designs to address sampling constraints, scoring of instruments, data analysis techniques, presentation of results, format of tables, and discussion of results. Uniform requirements for manuscripts<sup>6</sup> and statistical guidelines<sup>7</sup> cited in this journal's information for authors are additional sources for exemplars. Engle's Axioms (see Table 1) and exemplars can assist every researcher in attaining excellence in the planning, execution, and presentation of health science research.

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#### REFERENCES

1. Milisen K, Foreman MD, Abraham IL et al. A nurse-led interdisciplinary intervention program for delirium in elderly hip-fracture patients. *J Am Geriatr Soc* 2001;49:523-532.
2. Williams MA, Holloway JR, Winn MC et al. Nursing activities and acute confusional states in elderly hip-fractured patients. *Nurs Res* 1979;28:25-35.
3. Williams MA, Campbell EB, Raynor WJ et al. Reducing acute confusional states in elderly patients with hip fractures. *Res Nurs Health* 1985;8:329-337.
4. Burns G, Grove SK. *The Practice of Nursing Research: Conduct, Critique, and Utilization*, 3rd Ed. Philadelphia: WB Saunders, 1997.
5. Inouye SK, Bogardus ST, Charpentier PA et al. A multicomponent intervention to prevent delirium in hospitalized older patients. *N Engl J Med* 1999;340:669-676.
6. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *N Engl J Med* 1997;336:309-315.
7. Bailar JC, Mosteller F. Guidelines for statistical reporting in articles for medical journals. *Ann Intern Med* 1988;280:266-273.