

*Developing a Successful Grant Application:
Methods and Data Analysis Sections*

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General points to consider

- ◆ **Specific Aims** serve to organize how the reviewer thinks about the application
- ◆ Use them to **organize** and **integrate** all sections of the application, including the data analysis section
 - Number them
 - Label them
 - Rely on the labels

General points to consider

- ◆ **Capitalize on redundancy** -
 - Avoid the trap of trying to describe every analysis
 - Rather describe major approaches to each aim and any significant modifications for other analyses
- ◆ An approximate **answer** to **the right question** is preferable to an exact answer to the wrong question (Tukey)

Overview of the scenario

- ◆ Outpatient educational intervention for chronic stable angina
- ◆ Intervention delivered in groups
- ◆ Assignment to intervention and control made at the facility level
- ◆ Total number of facilities is 30
- ◆ Incomplete information on facilities prior to intervention program

Overview of Specific Aims

◆ **1.0 Self-Reported Health Status:**

— Management of CSA as measured by SAQ

◆ **2.0 Medical Outcome:**

— Emergency room visits, hospital admissions, cardiovascular death, and medication non-compliance

◆ **3.0 Predictors:**

— Patient and facility characteristics associated with success

◆ **4.0 Patient Knowledge :**

— Angina Knowledge Scale (linked to intervention)

Problems that must be addressed

Design: Assignment

- ◆ Assignment of facilities to treatment vs control
 - randomized at the facilities level with matching on key administrative variables (number of CSA admissions per year, and severity of coronary disease in patient population)
- ◆ Accumulation of patients into intervention groups
 - group size will be allowed to vary between 7 and 20 based on rolling admissions (start within one week)

Problems that must be addressed

Design: Conditions and Sampling Factors

- ◆ Group nature of intervention; does a group structure exist for the control? (ed. group)
 - Patients in control facilities will be grouped using similar enrollment strategy. Control condition will involve weekly mail-outs of “educational” information
- ◆ Can treating physician be ignored as a source of dependence among observations?
 - Expect yes conditional on patient covariates, but examine in analysis

Problems that must be addressed

Design: Assessment

- ◆ Should emergency room visits, admissions, cardiovascular death, and medication non-compliance be measured at the patient level or taken from administrative data?
 - Patient Level (ERV; HA; MNC; CVD-Post TX)
 - Facility Level (CVDH-Pre; CVDH-Post TX)

Problems that must be addressed

Design: Observations and Assessment

- ◆ Timing of assessments (varies by measure)
 - SAQ; Knowledge
 - * Pre, Post, 1 m post, 6 m post, 1 yr post
 - Medical Outcome (varies by outcome)
 - * Pre (last 12 m), 1 yr post (ERV; HA; MNC)
annually to 4 yrs. post (CVD-Hospital Level)
 - * 2 Year Post (CVD-Patient Level)
 - Patient Characteristics; TX Compliance; TX Fidelity
 - * Pre (PC); Post (TXC; TXF)

Design: Observations and Assessment (cont.)

◆ **Multiple scales of SAQ**

— form composite by

- * standardizing so that all scales have the same mean and variance at pre-test for the Control group
- * apply the same transformations to the Pre-Test for the Intervention group and all subsequent time points for both treatment groups
- * sum across scales within a time point

— **fixes the Control mean and variance at pre-test, but allows all other means and variances to differ**

Multiple scales of SAQ (cont.)

Alternatives

- Analyze individual scales adjusting type I error
 - * difficult to justify given nature of intervention and expected results
 - * may be difficult to model some scales given limited number of items per scale
- Treat scales as five indicators of a latent variable
 - * allows test of psychometric invariance
 - * complicated by non-normality from limited items
 - * more difficult to handle the 4-level multilevel structure

Overall Analysis Strategy for Continuous Outcomes (Aims 1.0 and 4.0)

- ◆ Multilevel Individual Growth Model with 4-levels (time, subject, ed. group, and facility) with random effects at the first three levels
- ◆ Intervention is incorporated as a fixed effect at the facility level.
- ◆ Greater dependence among observations within Intervention ed. groups suggests that variance components at level three (ed. group) may differ between Intervention and Control

Overall Analysis Strategy for Continuous Outcomes (cont.)

◆ **Aims 1.0 and 4.0:**

- Time invariant covariates include key patient characteristics: age, gender, race, pre-test SAQ, pre-test Knowledge
- Time varying covariates include time and patient knowledge (**Aim 1.0 only**)

Overall Analysis Strategy for Continuous Outcomes (cont.)

◆ **Aim 3.0:**

- **Patient-level Predictors** of success are tested as interactions of Intervention Group with Time invariant covariates (age, gender, race, pre-test SAQ, pre-test Knowledge)
- **Facility-level Predictors** will be examined individually (or as composites where feasible) due to the limited number of facilities and will rely on exploratory displays
- Analyses **within the intervention** group only will examine TXC and TXF as predictors of success

Overall Analysis Strategy for Discrete Outcomes at the Person Level

◆ **Aim 2.0:**

- the overall analysis method is similar to that applied for Aims 1.0 and 4.0, with three exceptions
 - * a Generalized Mixed Linear Models framework is used due to the discrete nature of the outcomes
 - * there is no time dimension to the model, only person, ed. group, and facility
 - * for cardio-vascular death measured at the patient level, there is no pre-test measure of the outcome, although other pre-tests covariates will be included

Overall Analysis Strategy for Outcomes Measured directly at the Facility Level

◆ **Aim 2.0:**

- the overall analysis method is that of repeated measures ANOVA with the pre-test measure used as a covariate and Intervention Group as a between subjects factor with two levels.
- The number of covariates must be restricted given the overall sample size

Summary and Conclusions

- ◆ The overall study presents a number of challenges:
 - multiple scales for the SAQ
 - the limited number of facilities
 - the delivery of the intervention in groups, with likely weaker dependence in the control condition
 - the use of discrete and continuous outcomes, and the challenge of directly measuring some facilities level outcomes meaningfully (i.e., not as aggregated person level outcomes)

Summary and Conclusions (cont.)

- ◆ The general approach recommended given the design decisions:
 - uses multi-level and generalized mixed linear models
 - incorporates a group structure to the random effects
 - treats Intervention as a fixed effect at the facilities level
 - examines the role of patient characteristics as predictors by examining interactions between patient level characteristics and Intervention group
 - examines the role of facilities level characteristics as predictors individually, and use exploratory techniques