PRE-ANALYSIS PLAN CHECKLIST
VEDASTE NDAHINDWA | UNIVERSITY OF RWANDA

2016 EAST AFRICA IMPACT EVALUATION WORKSHOP AND EVIDENCE SUMMIT

CEGA
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OVERVIEW

1. What, why, and when?
2. Basic outline for PAPs and what to include
3. Trial registration
4. Advice for post-PAP changes to study
• What is a Pre-Analysis Plan?
  • Document outlining the technical details of a study to be conducted
    • Includes justification for the study
  • IRB protocol and final manuscript
  • Also known as a “research protocol” or “study protocol”

• Why write one?
  • Raise the credibility and reliability of research results
  • Protects you against stakeholders who may be interested in doubting your results

• When to write one?
  • Ideally, before baseline
BASIC OUTLINE FOR PAPS (HEAVILY BASED ON SPIRIT GUIDE)

1. General information
2. Introduction
3. Study Design
4. Pre-specification of analytical decisions
5. Expected issues
6. Conclusion
GENERAL INFORMATION/INTRODUCTION

- Make clear who’s doing the research and justification for the study
- General information
  - Title
  - Researchers involved
    - Name, Title, Department, Institution
  - External partner institutions
  - Project staff (optional)
  - Potential conflicts of interest
- Introduction
  - Describe gaps in current knowledge, and how this study fills those gaps (i.e. literature review)
STUDY DESIGN

• Describe hypotheses and how treatment effects will be measured:
  • All hypotheses which will be tested
  • Main variables of interest + measures
  • Primary and secondary outcomes distinction
• Preliminary studies (if applicable)
  • Is this study part of a series?
• Basic methodology
  • RCT, natural experiment, discontinuity design, etc?
  • Blind, double-blind, or unblinded?
STUDY DESIGN

- Study design details
  - Region
  - Research population
  - Sampling frame
  - Inclusion/exclusion criteria (with justification)
  - Unit of analysis and definition of cluster
  - Attrition criteria
  - Early termination criteria for study
  - Expected timeline (implementation, data collection, etc).
STUDY DESIGN

• Intervention details
  • All hypotheses which will be tested
  • Main variables of interest + measures
  • Primary and secondary outcomes distinction

• Data collection
  • Source(s) of data
  • How data will be collected (e.g. in-person surveys, phone, administrative data) and rationale

• Randomization procedure
  • How will it be conducted? E.g. through STATA? Physical lottery?
  • Unit of randomization and justification
  • Stratification variables if included
STUDY DESIGN

- Blinding (if applicable)
  - Who will be blinded
  - Procedures to ensure blinded individuals will not have access to treatment status II hypotheses which will be tested

- Power Calculations
  - Justification of adequacy of sample size, estimated effect size
STUDY DESIGN

- Flow charts are handy (though not required)

Example study design flow chart:

- Informed Consent
- Screening
- Randomisation ($n = \text{sample size}$)

**ACTIVE ARM**
- Daily dosing
  - Weekly assessments
- 4-weekly assessments

**CONTROL ARM**
- No dosing
  - Weekly assessments
- 4-weekly assessments

{Treatment period (6 weeks)}
{Follow-up period (12 weeks)}

Source: Murdoch Children’s Research Institute 2009
ANALYTICAL SPECIFICATIONS

- If variables will be constructed (e.g. creating index variables) how will they be constructed?
  - Not always known, but write what you expect

- What are the primary model specifications?
  - One of the key elements in “tying one’s hands”

- If multiple hypothesis testing will be done, how will this be accounted for in the analysis?
EXPECTED ISSUES AND CONCLUSION

- Any relevant issues to be expected over the course of the study and procedures for how the research team will deal with them. For example:
  - Lower-than-expected initial take-up of treatment
  - Non-compliance of participants
  - Spillover effects
  - Surveyor effects/issues

- Conclusion
  - Similar to conclusion section in final manuscript
TRIAL REGISTRATION

- Should be done before implementing baseline
- Where to register depends on the academic field
  - J-PAL and IPA require that studies be registered with the AEA Registry
- Other registries/resources include:
  - EGAP
  - RIDIE at 3ie
  - Open Science Framework
  - Clinicaltrials.gov
  - PubMed
  - SPIRITguide
    - Similar to CONSORT for RCTs but applied to study protocols
CHANGES POST-PAP PUBLICATION

- **Be as transparent as possible!**
- Changing the PAP itself
  - Can be done, but should be done only if there is a public record of the version changes (e.g. OSF, Clinicaltrials.gov)
- Recording changes in the final manuscript/publicly accessible reports
  - Address that there are differences and provide explanation, e.g.:
    - Changes in the way some outcomes are measured because of problems with equipment or because better measures had been found through other research
    - Reduction in sample size because of civil unrest and providing new power calculation to address power adequacy
REFERENCES/RESOURCES


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