Writing a Pilot or Feasibility Study

“You never test the depth of a river with both feet”
What a pilot study is not.

- It is not a study you undertake when you have no hypothesis.
- It is not a study that has a sample size that is too small to matter.
- It is not a small, underpowered clinical trial...”pilot” does not make it ethical.
- It is not a study that has no follow-up planned.
What is a pilot study?

- A miniature version of the main study run to determine if the components and processes can all work together to generate results
- A shake-down cruise of the main study
- Focused on procedures: recruitment, randomization, follow-up visits
- Tends to be methodologically more rigorous than “feasibility” studies
- Particularly important for complex interventions
Types of Pilot Studies

- Internal pilot = data will be incorporated
- External pilot = data will not be used

- Can help you to recalculate power, sample size
What is a feasibility study?

- Pieces of research done prior to the main study to answer the question, “Can this study be done?”
- Undertaken *before the real work* to determine whether to proceed with a project and to decide the best approach to adopt
- Important in reducing uncertainties for the main study, can provide reassurance to funders that the work has been thoroughly thought through
Feasibility Study

The endpoints for a feasibility study are factors that affect successful trial conduct, not measures of treatment effect or safety.

- What do we need to know that we currently don’t in order to make the main study a success?
- What could go wrong in the main study?
- This is not a “study in miniature”
Feasibility Study Questions

**Study Participants**
- How easy are they to identify?
- Can you demonstrate you have access to sufficient subjects?
- How diverse/similar are the subjects?
- How realistic are the eligibility criteria?
  - Is it obvious who meets and who does not meet the eligibility requirements?
- How willing would they be to be recruited and/or randomized?
- What is the refusal rate?
Think about the CONSORT diagram....
Feasibility Study Questions

**Study Investigators**

- How suitable are the investigators in terms of qualifications, experience, probity?
- What facilities and staff do they have at their center that help the study?
- How well did they recruit patients as an indicator marker of what might happen in the main study?
- How willing are they to recruit or randomize patients when faced with alternatives?
Feasibility Study Questions

Study Processes

- Retention rates
- (Non)compliance or adherence rates
- Understanding of study questionnaires or data collection tools:
  - Do subjects provide no answer, multiple answers, qualified answers, or unanticipated answers to study questions
  - Run a cognitive test of selected instruments
A chance to involve the community?

- Community of clinics/practices and the patients from those practices
- Can help to determine:
  - How the intervention will be implemented
  - How frequently patients may return for follow-up
  - How best to collect information
Feasibility Study Questions

Power and Sample Size

- How frequently does the outcome occur in the population I expect to recruit from? (baseline)
- Expected range of the outcome, sample variance
- What is the variability of other important variables?
Questions more specific to pilot studies

- **Determining capacity:**
  - Will the study participants overload your phone lines or overflow your staff’s capacity to recruit and perform study visits?

- **Determining process time**
  - How much time does a study visit take?
  - Is the equipment readily available?
  - What backup is available?

- Can the software used for capturing data read and understand the data?

- **Determining center willingness and capacity**
  - Do the centers do what they committed to doing?
  - Do investigators have the time to perform the tasks they committed to doing?
  - Are there any capacity issues at each participating centre?
Questions more specific to pilot studies

Management:

- What are the challenges that participating centers have with managing the study?
- What challenges do study personnel have?
- Are there any problems entering data into the computer?
- Can data coming from different sources be matched?
- Were any important data values forgotten about?
- Do data show too much or too little variability?
Questions specific to pilot studies

Scientific:
- Is it safe to use the study drug/intervention?
- What is the safe dose level?
- Do patients respond to the drug? (maybe not best question)
- What is the estimate of the treatment effect?
- What is the estimate of the variance of the treatment effect?
Example of feasibility SA

- To determine adherence rates to the risk assessment model and standardized order form
  - Definitely feasible = completed for ≥70% eligible
  - Possibly feasible = completed for 50-69% eligible
  - Not feasible = completed for <50% eligible

- To determine rates of appropriate prophylaxis achieved using the VTE risk assessment and standardized order form
  - Definitely feasible = >25% relative increase in the proportion of at risk patients receiving appropriate prophylaxis

- To explore the attitudes of health providers towards the intervention
Writing a feasibility study

- A description of a clear route of progression to the main study is paramount
- Usually no hypothesis testing
- Specific aims need to clearly delineate the steps you are undertaking, why, and what success means
- Power calculations are usually unnecessary
  - However, the sample size should be adequate to estimate parameters such as recruitment rate and sample variability
Writing the study outcomes

- State the criteria for success *a priori* – benchmarks for success
  - Stop
  - Continue but modify protocol
  - Continue but monitor
  - Continue, no change