When Things Go Wrong

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Sometimes Things Go Wrong

Despite our best efforts, sometimes things do not go as planned

Covid is the extreme example, but disasters happen all the time

Attrition
Schools drop out of the study
Classrooms or teachers drop out of the study
Students drop out of the study

Measurement Problems
Planned outcome data cannot be collected
Planned covariates cannot be collected or collected “on time”

Sometimes Things Go Wrong

Implementation Problems

Implementation varied substantially across schools or classes

Only some of the treatment was implemented

The treatment was implemented badly in some or all sites

Unexpected Big Shocks to the System

Acts of God (floods, hurricanes, tornados, Covid)

Human tragedies …

You simply cannot anticipate or plan for the last category of causes

Things for Which You Can Plan

The best solution is to make sure bad things don't happen

Do your homework!

Learn as much as possible about each site before the start of the study

You might decide that some sites are too risky (prone to instability) to include in the study

This can help you anticipate measurement and implementation issues

Knowing why there may be problems can help you head them off before they happen

Things for Which You Can Plan

Keep doing your homework!

Know what is going on in the sites, not just in your study, but overall

Problems usually emerge over time and sometimes you can take action to keep them from harming your experiment

Having confidants (e.g., site coordinators) at each site is very helpful

Having some of your staff whose job is to keep track of specific sites (like “case workers”) is useful—their job is to spot emerging problems so they can be tackled before it is too late

What is this Talk About?

This is not a talk with many answers. We can, however, provide you with a framework and some suggestions that we hope will spur your creativity when a problem arises

Think about:

- What effects will this have on randomized trials?
- Should a study proceed?
- Approaches that might be taken to problems
- Validity concerns
- Considering what to do

How to think of it depends on the point in the study that the problems (disruptions) arise

Case 1: Disruption at the Beginning of a Project

(Perhaps your study was funded or began in Fall 2020)

Problems you might be facing:

- Uncertain or failed recruitment
- Inability to collect baseline data
- Inability to conduct training
- Changes to business as usual and feasibility/utility of the intervention

Case 2: Disruption Occurred in the Middle or End

(Perhaps you were funded prior to 2020 and were already 'in the field' when COVID arrived)

Problems you might be facing:

- Inability to complete treatment implementation
- Inability to collect mediators or implementation data
- Inability to collect posttest or follow-up data

All of these likely result in smaller than expected sample size.

Case 3: Disruptions to Multiple Cohorts

(Perhaps your study was mostly finished, leaving only one cohort affected)

Problems you might be facing:

- Study budget limitations
- Comparability of data across time (before and after disruption)
- Generalizability concerns post-pandemic

Should the Study Proceed?

Is it scientifically appropriate to proceed?

- Can the (probably modified) study be a contribution to knowledge, given the changed context of education?

Is it feasible to proceed?

- Can the study, as modified, be completed with the available resources?

Is there enough scientific value to justify proceeding?

- Is there an adequate scientific return on investment (ROI) to justify proceeding?

To answer these questions, you must know how the study could be modified to address disruptions.

Broad Strategies to Address Problems

Delay the Startup of the Study until Things Stabilize

At first, this seemed like the most reasonable strategy, but

The effects of COVID continued to affect schools for years, many other large disruptions will continue afterwards

Some disruptions are too big to “wait out”

You will still likely need to retool your study in some way.

Address Design Sensitivity Concerns

1. Is it possible to increase design sensitivity?

2. Accept a low power RCT

3. Shift to focus on effect size rather than statistical significance

4. Use Bayesian approach with prior information

Change the Measurement Design

First, be aware of the measurement technology for linking and equating tests.

1. Collect delayed posttest data, possibly from a subset of units.
2. Pool data across different measures of the same outcome construct meta-analytically.
3. Use proxy dependent variables (e.g., formative assessments, etc.) but be aware of impact of misalignment and unreliability on power.

Collect the Posttest Data on a Subset of Individuals

Number of Clusters	Cluster Size	Total N	Effect Size	Power
50	100	5000	0.25	0.78
50	80	4000	0.25	0.77
50	50	2500	0.25	0.77
50	40	2000	0.25	0.77
50	30	1500	0.25	0.76
50	20	1000	0.25	0.75
50	10	500	0.25	0.72
50	9	450	0.25	0.71
50	8	400	0.25	0.71
50	7	350	0.25	0.69
50	6	300	0.25	0.68
50	5	250	0.25	0.66

Effects of Misalignment and Unreliability on Power

reliability of proxy

reliability of intended measure

proxy-intended correlation

Number of Clusters	Cluster Size	Total N	Effect Size	$\rho_{PP'}$	$\rho_{II'}$	$\rho_{IP}{}^{a}$	Power
50	100	5000	0.25	1.0	1.0	1.0	0.78
50	100	5000	0.25	1.0	1.0	0.8	0.58
50	100	5000	0.25	1.0	1.0	0.6	0.37
50	100	5000	0.25	1.0	1.0	0.5	0.27
50	100	5000	0.25	1.0	1.0	0.4	0.19
50	100	5000	0.25	1.0	1.0	0.3	0.13
50	100	5000	0.25	1.0	1.0	1.0	0.78
50	100	5000	0.25	0.9	1.0	0.95	0.73
50	100	5000	0.25	0.8	1.0	0.89	0.68
50	100	5000	0.25	0.7	1.0	0.84	0.63
50	100	5000	0.25	0.6	1.0	0.77	0.55
50	100	5000	0.25	0.5	1.0	0.71	0.49

Change the Focus of the Study

You might convert your study, including to:

1. One focused on further development of the intervention
2. A methodological or measurement study
   - Craft knowledge about randomized trials is in short supply
3. A descriptive study
   - Tough but not impossible for quantitative types
4. A study of a different intervention opportunistically
   - The COVID pandemic and its effect can be the intervention?

Change to Within School Randomization

Design	Number Clusters	Cluster Size	Total N	Effect Size	Power
Hierarchical (CRT)	50	100	5000	0.25	0.78
RBD Blocks Random	25	200	5000	0.25	0.84
RBD Blocks Fixed	25	200	5000	0.25	>0.99
Hierarchical (CRT)	40	100	4000	0.25	0.68
RBD Blocks Random	20	200	4000	0.25	0.75
RBD Blocks Fixed	20	200	4000	0.25	>0.99
Hierarchical (CRT)	40	20	800	0.25	0.67
RBD Blocks Random	20	40	800	0.25	0.74
RBD Blocks Fixed	20	40	800	0.25	>0.99
Hierarchical (CRT)	40	20	800	0.25	0.65
RBD Blocks Random	20	40	800	0.25	0.72
RBD Blocks Fixed	20	40	800	0.25	0.98

Change to a Quasi-experiment

This is a very radical change:

- It is much harder to conduct a good quasi-experiment than a good randomized experiment
- Data requirements will be different (and more extensive)
- Personnel needs will be different

Fortunately, there is a big literature, starting with the literature on "broken" randomized experiments.

Considerations

Validity Considerations

Recall the Shadish-Cook-Campbell framework:

- Statistical conclusion validity
- Internal validity
- External validity
- Construct validity of cause and effect

Evaluating Strategies and Practical Considerations

Once a trial is funded:

- A large financial investment has already been made
- A large investment in person time has been made

How can we assure that the scientific return is likely to be commensurate with that investment?

- It is a complex judgment that needs to be made with approval of program officers
- IRBs need to be involved too if there are substantial changes!

Don't expect funders to be enthusiastic about offering more money.

If Bad Things Do Happen

Face up to it! That is the only way you can plan rationally

Think about what you can salvage from the study—Covid forced a lot of people to do just this

(See the paper by Hedges and Tipton which we included among the readings for this Institute)

After you have given it a lot of thought, but without too much delay, talk to you program officer

Program officers care about their grants and often have good ideas

Realize that there is a limit to what program officers can do (e.g., ask for advice, not more money)

Remember

Bad things sometimes happen, even if you are a competent researcher, have a good plan, and have been capturing good intelligence from all your sites

You want to be sure you make clear what you have done that demonstrates good research practice, beyond that, it is just not your fault

Covid was a wake-up call about this

But, disasters don’t happen very often

Be prepared, but don’t expect disaster

Thank You!